U.S. Department
of Transportation

**Federal Aviation
Administration**

Aircraft Certification Systems Evaluation Program (ACSEP) FY 1999 Report

Prepared by

Aircraft Certification Service

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EXECUTIVE SUMMARY

This report documents the fiscal year (FY) 1999 results of the Federal Aviation Administration (FAA) Aircraft Certification Service (AIR) Aircraft Certification Systems Evaluation Program (ACSEP).

The ACSEP was designed to determine if FAA production approval holders, their priority parts suppliers, and delegated facilities are complying with the requirements of applicable Code of Federal Regulations (CFR) and the procedures established to meet those requirements. It also surveys the application of standardized industry practices, not required by the CFR or FAA-approved data, to identify national trends that may require development of new or revised regulations, policy, or guidance. The elements of the evaluation are referred to as criteria. Data was collected on noncompliance and applicability with respect to those criteria. The history and background of ACSEP, the structure of the evaluation teams, and departmental interactions are discussed in *Appendix A.*

During an ACSEP evaluation, the actual operating practices of a facility are compared to the CFR, FAA-approved data, and the facility's internal procedures. Any inconsistency discovered (termed "issue" in this report) is classified and recorded. An issue is classified by its type and the system element under which it is noted. There are five issue types:

Safety Finding - an issue that compromises immediate continued operational safety.

Systemic Finding - an issue that is systemic in nature, i.e., is pervasive, repeatable, or represents a breakdown in the quality management system. For an issue to be categorized a finding, it must also be a noncompliance to a CFR or FAA-approved data (or noncompliance with the procurement instrument when a facility is a supplier).

Systemic Observation - an issue that is systemic in nature and is a noncompliance to facility procedures that are not FAA approved.

Isolated Observation - an issue that is of an isolated or nonsystemic nature, i.e., isolated to a particular person and/or timeframe and does not represent a breakdown in the quality management system. For an issue to be categorized an isolated observation, it must also be an isolated noncompliance to a CFR or FAA-approved data (or a noncompliance with the procurement instrument when a facility is a supplier).

CFR-Based Observation - the discovery of FAA-approved data that is inconsistent with the CFR.

Issues are classified using system elements. In total, there are 17 system elements that represent a quality management system for a production approval holder:

- Organization and Responsibility
- Design Data Control
- Software Quality Assurance
- Manufacturing Processes
- Special Manufacturing Processes
- Statistical Quality Control (SQC)
- Tool and Gauge
- Testing
- Nondestructive Inspection
- Supplier Control
- Nonconforming Material
- Material Handling/Storage
- Airworthiness Determination
- FAA Reporting Requirements
- Internal Audit
- Global Production
- Manufacturing Maintenance Facility

There are 10 system elements that represent a quality management system for a delegated facility:

- Organization and Responsibility
- Design Data Approval
- Testing
- Airworthiness Certification
- Continued Airworthiness
- Project Management
- Design Change Approval
- Conformity Inspection
- FAA Notification
- Audit

Each system element is further divided into "criteria." To fully examine the detailed areas within each of the 17 system elements, the criteria were developed with extensive assistance from industry. A process also exists to identify potential new criteria should the existing criteria not address a particular functional area within a system element. The subclassification of issues into the detailed criteria allows the FAA to identify specific areas of concern and allows industry to focus corrective action on those specific areas of concern. For example, the supplier control system element is composed of 16 individual criteria. Specific areas of concern that may be identified include: the use of approved suppliers, periodic evaluations of suppliers, flowdown of applicable technical and quality requirements to suppliers, raw material verification, and others.

Through the use of detailed criteria and their relevant system elements, quality management systems can be evaluated in a consistent manner. Annually, the data is collected and analyzed for trends. In FY 1995, the data was baselined so that the effectiveness of any industry actions to address issues previously reported can be detected and measured. Where appropriate, the analyses presented in this report were performed at both the criteria and the system element level.

Analysis Results and Conclusions

Of the 646 findings and observations recorded at the 473 facilities evaluated in FY 1999, only 2 identified significant safety concerns, i.e., findings for which immediate corrective action was required. Both were for failing to report to the FAA failures, malfunctions, or defects on safety critical assemblies. Another, more significant trend has also developed recently. For two consecutive years, a safety finding was reported for insufficient inspection methods and plans to ensure that parts were inspected for conformity with FAA-approved design data. What amplifies these two safety findings is that this is also the third most frequent area for nonsafety related issues. Additional details are in *Section 3.1* of this report.

The balance of the issues reported were not considered an immediate safety concern. The data collected did, however, indicate some very definite trends with these nonsafety issues. More than one-fourth of all findings and observations were recorded in the manufacturing processes system element: the most problematic area for all of the production approvals. One-half of the findings and observations were recorded within five additional system elements: supplier control, design data control, tool and gauge, nonconforming material, and special manufacturing processes. In addition, the issues within these system elements were concentrated within a few criteria.

The system elements and criteria where the most issues were reported are as follows:

Manufacturing Processes - Specific functions and operations necessary for the fabrication and inspection of parts and assemblies (e.g., machining, riveting, and assembling).

- Completed products/parts did not have proper identification markings.
- Insufficient inspection methods and plans to ensure that parts were inspected for conformity with FAA-approved design data.
- Work instructions did not adequately control the manufacturing process.
- Records were not generated or maintained for all significant provisions of the quality/inspection program which have an effect on control of FAA-approved design data, or if applicable, purchase order requirements.
- The evaluated facility was operating outside the limits of their production approval.

Supplier Control - The system by which the evaluated facility ensures that supplier materials, parts, and services conform to FAA-approved design. For the purpose of this section, the term "supplier" includes distributors.

- Initial and periodic evaluations of suppliers were not made, as necessary, or corrective actions were not taken to correct system deficiencies.
- Receiving inspection did not verify that supplier-furnished parts/services conformed to FAA-approved design data.
- Raw material, including process material (such as weld rod, etc.) was not verified or identified.
- The evaluated facility did not flow down applicable technical and quality requirements to suppliers, both in the U.S. and in other countries.
- Unapproved or unqualified suppliers were used. Suppliers were not assessed to established minimum acceptability criteria.

Design Data Control - The planning and integration of the evaluated facility's procedures for continuously maintaining the integrity of design data, as approved by the FAA or FAA-delegated representatives, in the completed product. This includes software used in type-certificated aircraft or related products (airborne software).

- The issuance, retrieval, distribution, and currency of design and technical data was not controlled.
- The facility lacked a drawing control system.

Tool and Gauge - The function which establishes control of precision measuring devices (e.g., tools, scales, gauges, fixtures, instruments, or automated measuring machines) used in fabrication, special processing, inspection, and testing of detail parts, assemblies, and completed products to determine conformity to FAA-approved design.

- Tools and gauges were not initially approved or were not periodically inspected and calibrated.

Nonconforming Material - The method of controlling, evaluating, and dispositioning of any part/product which does not conform to FAA-approved design.

- Nonconforming parts/products were not identified, controlled, or dispositioned.
- Material review records were not generated or controlled.

Special Manufacturing Processes - The methods whereby materials, parts, or assemblies are worked or fabricated through a series of precisely controlled steps, and which undergo physical, chemical, or metallurgical transformation (e.g., heat-treating, brazing, welding, and processing of composite material).

- Special processes were not accomplished in accordance with the established process specifications.

The first five of the above six system elements have been the most predominant areas for issues since a baseline for the data was set in FY 1995. A more detailed analysis of these trends is presented throughout *Section 3* of the report.

Whereas the various types of manufacturing facilities have issues in the same areas, there was a difference in the rate that these were reported at the various production approval holders. TSO authorization holders appear to have a higher noncompliance rate than the other two approval types. PC and PMA holders appear to be similar in their compliance rates. *Section 3.5* provides more detail into the similarities and differences among various manufacturing facilities.

Since FY 1995, the combined factor of facility size and quality system complexity has been demonstrated as a key factor in the number of findings and observations recorded. A small facility with simple systems will, on average, have a better compliance rate than a large facility with complex systems. *Sections 3.5 through 3.10* of this report provide more detail into the similarities and differences among various facilities.

Significant insight has been gained into the influence that internal audit programs have on general compliance. Large facilities with complex systems that have an internal audit program in place appear to have fewer findings and observations than facilities of an equal size and complexity that do not have internal audit programs. Small facilities with simple systems do not appear to have such a difference. Simply implementing an internal audit program, however, is not sufficient. The internal audit program must be compliant with those procedures that define it. Should the internal audit program be noncompliant with its own procedures, a loss of quality management control can occur within the areas that internal audit is attempting to monitor. Facilities which were found to be in noncompliance with their own internal audit procedures were sixteen times more likely to have systemic issues in other areas. In fact, nearly every facility that was not following its internal audit procedures had additional findings in other areas. Also, those facilities that violated their own internal audit procedures had twice the number of findings and observations than those facilities following their own internal audit policies and procedures had. Both industry and the FAA should carefully consider the implications of this trend. The analysis and its detailed findings are presented in *Section 3.9*.

Prompted by industry questions concerning why supplier control continues to be a major area of noncompliance, a major analysis effort was undertaken. The encountered condition for every reported supplier control issue was carefully read and analyzed. Some definitive trends were discovered. The large majority of the issues could be categorized into six distinct areas. These areas were not the same for the various approval types. The bulk of the issues could be grouped into just three different areas for each of the various approval types. These areas and their associated approval types are:

PC holders

- A general failure to flow down applicable technical and quality requirements to suppliers
- Performing tasks to unapproved or outdated procedures
- Failure to control the suppliers' design data

PMA holders

- Use of unqualified suppliers
- Failure to re-survey suppliers on schedule in order to determine their capability to meet requirements
- Inability to trace the physical properties of raw material

TSO authorizations

- Use of unqualified suppliers
- Failure to re-survey suppliers on schedule in order to determine their capability to meet requirements
- Performing tasks to unapproved or outdated procedures

The FY 1998 ACSEP analysis results were discussed at the April 1999 meeting between the FAA and the Manufacturing, Maintenance, & Repair Committee (MMRC) of the industry groups Aerospace Industries Association (AIA) and the General Aviation Manufacturers Association (GAMA). Based upon the analysis results, the MMRC agreed to form a team, in cooperation with the FAA, to attempt to formulate plans to reduce findings and observations. The team is composed of both FAA personnel and industry experts. They are examining the ACSEP criteria and system elements. Their goal is to identify and consolidate criteria that are redundant or mask other issues. Additionally, they are investigating whether any criteria need to be added to address any areas not currently addressed by the current criteria.

Two joint FAA and industry teams were also established in FY 1998. Those two teams are focusing on supplier control and internal audit. The supplier control team is developing a plan to reduce findings and observations in supplier control processes. The internal audit team has published an industry best practice document on internal audit quality programs (available on the Internet at http://www.faa.gov/avr/air/air200/Bestprac.htm). This document provides information that may be used to design and implement an internal quality audit program. This document also incorporates a section on corrective action that discusses the role of root cause corrective action in addressing quality system deficiencies. Although the document is targeted at production approval holders, the procedures and practices outlined in the document can be applied to all aerospace industry manufacturers.

Two significant policy changes had a dramatic effect on how ACSEP evaluations are scheduled at the various types of facilities. Based upon the guidance of the Gore Commission on Reinventing Government (GCRG), changes to the process of supplier surveillance were implemented. Supplier surveillance will be conducted using principal inspector (PI) audits and cooperative support from Civil Aviation Authorities in other countries, rather than through ACSEP evaluations. Audits will now examine the flow down of purchase order requirements from the production approval holders and the suppliers' compliance with those requirements. Particular attention will be placed on the four most troublesome system element areas identified by the annual ACSEP report, and any special emphasis items from the production approval holder's last ACSEP evaluation.

The second policy change during FY 1999 was also one of the most sweeping changes to have occurred for ACSEP: Resource Targeting. The design of Resource Targeting began in 1994 as a GCRG initiative with the following objective: use a systematic, analytic approach to focus the FAA's limited resources on evaluating those facilities with the greatest potential safety impact. The main way this objective was to be met was to adjust the frequency at which facilities would be evaluated. Prior to Resource Targeting, facilities were scheduled for evaluation according to the type of production approval that they held. By contrast, Resource Targeting uses a process of assessing quality system strength and inherent risk associated with each facility. Those facilities with the greatest perceived risk are scheduled for evaluation more frequently than facilities with less perceived risk. By focusing resources on those production approval holders with the most risk, 13 percent fewer ACSEP evaluations are required annually. In combination with the elimination of suppliers from the ACSEP evaluation schedule, 27 percent fewer ACSEP evaluations are scheduled each year.

The continuous improvement initiatives implemented in ACSEP have resulted in a steady reduction in difficulties encountered during ACSEP evaluations over the last six years. Evaluation teams in FY 1999 reported 96 percent fewer problems in interpreting and utilizing the ACSEP order and performing evaluations than in FY 1994. In addition, there have been continuous improvements in customer satisfaction with ACSEP evaluations. As part of the ACSEP continuous improvement process, the facility's management is provided with a feedback report on which to record their assessment of the conduct of the evaluation team. All phases of an ACSEP evaluation are addressed from pre-evaluation notification through post-evaluation review of any findings and/or observations. Less than one percent of the facilities returning a feedback report in the last three years have reported dissatisfaction with the conduct of the ACSEP evaluation teams. See *Section 4* for additional information on the continuous improvement program of ACSEP.

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FY 1999 Report

1. Introduction

This report summarizes the results of the Aircraft Certification Systems Evaluation Program (ACSEP) and provides a comprehensive view of the program's results from October 1998 through September 1999. The analysis of the data provides insight into procedural compliance trends with production approval holders and highlights some specific areas of concern.

Order 8100.7, Aircraft Certification Systems Evaluation Program, was released in its final form in March 1994. Prior to this, a draft version was used to perform the evaluations and to collect data. The final order contained some significant changes in the categorization and interpretation of the individual criteria and the method of recording evaluation results. Therefore, data collected for FY 1994 and earlier is not comparable to the data collected after the revised order was published (except in a very general nature).

The FY 1995 ACSEP report is considered the baseline from which all time-related trend analyses are established. With the collection of five years worth of comparable data, this report is the first to present detailed trend analyses.

1.1 Report Structure

Section 1 provides an introduction and overview of the program status. The reader is encouraged to read *Section 1.3*. This section gives the details of significant events that have occurred within the fiscal year. Many of these significant events have dramatically changed the way data is collected and therefore analyzed. Much of the background contained in *Section1.3* will be necessary to fully understand the balance of the report.

Section 2 provides summary conclusions of the analyses discussed throughout this report.

Section 3 provides a consolidation of the analyses that led to the conclusions presented in *Section 2*.

Section 4 provides the results of the ACSEP improvement effort including feedback from industry, lessons learned, and comments received regarding the ACSEP evaluations.

There are five appendices providing: a brief history and background of ACSEP; a list of definitions; detailed data regarding the specific findings and observations; a look into the relationship between the complexity of a facility’s quality control system and the probability of findings and observations; and an explanation of some of the analysis methods.

1.2 Program Overview of ACSEP

This subsection provides an overview of the ACSEP and a brief history of its growth. The ACSEP was developed as a result of numerous years of experience with Quality Assurance Systems Analysis Review (QASAR) audits and observations made during an interim audit program called "Operation SNAPSHOT." The most significant differences between QASAR and ACSEP are:

a) ACSEP evaluations are performed in accordance with consistent and standardized evaluation criteria.

b) The evaluation criteria used during an ACSEP evaluation were developed with extensive input and cooperation from the aviation industry to ensure that emerging technologies were addressed.

c) ACSEP evaluation results are maintained in a centralized database that allows statistical trend analysis.

d) An annual report of the aggregate ACSEP evaluation results is published.

e) ACSEP actively incorporates the evaluation of facilities with engineering delegations. The facilities that are evaluated by ACSEP are:

- Approved Production Inspection System (APIS)
- Production Certificate (PC) and Production Certificate Extension (PCEX)
- Parts Manufacturer Approval (PMA)
- Technical Standard Order (TSO) authorization
- Delegation Option Authorization (DOA)
- Designated Alteration Station (DAS)
- Special Federal Aviation Regulation No. 36 (SFAR-36)

A more detailed history and background of ACSEP, the structure of the evaluation teams, and departmental interactions are discussed in *Appendix A*.

1.3 Significant Events During the Fiscal Year

The following significant events either changed policy that affects the structure of ACSEP or the analysis results, are improvement measures that are intended to reduce findings and observations, or are significant activities initiated as a result of ACSEP evaluation activity.

1.3.1 Removal of Suppliers from the ACSEP Evaluation Schedule

Early in FY 1999, the FAA examined the process of supplier surveillance. Based upon the guidance of the Gore Commission on Reinventing Government, changes were implemented. Supplier surveillance will be conducted using principal inspector (PI) audits rather than through ACSEP evaluations. The PI audits will consist of an audit of the purchase order requirements, the four most troublesome system element areas identified by the annual ACSEP report, and any special emphasis items from the production approval holder's last ACSEP evaluation.

Approximately 120 supplier evaluations were removed from the ACSEP evaluation schedule as a result of this policy change. This represents a 17 percent reduction in the total number of ACSEP evaluations performed each year. Since the number of supplier evaluations done in FY 1999 is so small and not representative of the whole supplier population, no analysis for FY 1999 is presented in this report.

1.3.2 Full Implementation of Resource Targeting

The most significant event to affect ACSEP during FY 1999 was also one of the most sweeping changes to have occurred for ACSEP: Resource Targeting. The design of Resource Targeting began in 1994 with the following objective: use a systematic, analytic approach to focus the FAA's limited resources on evaluating those facilities with the greatest potential safety impact. The main way this objective was to be met was to adjust the frequency at which facilities would be evaluated. Prior to Resource Targeting, facilities were scheduled for evaluation according to the type of production approval that they held. By contrast, Resource Targeting uses a process of assessing the risks and scheduling those facilities with the greatest perceived risk more frequently than facilities with less perceived risk. Annually, each approval holder is assessed with 21 safety factors. Additionally, the criticality of the parts they manufacture is categorized according to the safety impact any potential failure could have on continued operational safety. The 21 safety factors are split into two groups: system strength and inherent risk. System strength is a measure of how capable the quality system is for ensuring that parts will be manufactured according to FAA-approved data. Inherent risk measures the risk that a part failure would have on continued operational safety.

By focusing resources on those production approval holders with the most risk, 13 percent fewer ACSEP evaluations at production approval holders are required annually. In combination with the elimination of suppliers from the ACSEP evaluation schedule, 27 percent fewer total ACSEP evaluations are scheduled each year. This enabled the FAA to shift resources to other safety critical activities.

1.3.3 Initiation of the DOA, DAS, SFAR-36 (DDS) Program

The DDS program is reviewing existing ACSEP criteria for the evaluation of delegated facilities only and developing new criteria to improve the oversight and evaluation of delegated facilities. In addition, criteria for a technical evaluation have been created. The

technical evaluation focuses on the delegated organizations' methods and processes used in making findings of compliance, conformity, and airworthiness determinations. Between FY 2000 and FY 2001, 20 facilities will participate in the prototype phase of the program. Those facilities participating in the prototype will not have their delegation systems evaluated by the current ACSEP criteria. In lieu of the ACSEP evaluations, technical evaluations will be performed by DDS team members.

Revisions to the policy for FAA surveillance of delegated facilities will be ongoing throughout the prototype phase of the program. New policy reflecting the lessons learned during the prototype phase will be issued at the conclusion of the prototype phase. Another phase of the DDS program will assess the ability of the criteria to facilitate the analysis of trends. The goal is to use the DDS program as a learning step along a path towards possible implementation of the Organization Designation Authorization (ODA) process.

The net effect of the DDS activity is a comprehensive change to the portion of the existing ACSEP program that evaluates and analyzes the compliance of delegated facilities. The current ACSEP criteria will no longer directly compare with the new criteria developed by the DDS team. The lack of a consistent basis for trending, coupled with the low number of delegated evaluations performed during FY 1999, does not support the presentation of trend analysis for delegated facilities within this report. Consequently, little — other than what is in *Section 1.4* and in *Appendix C*—will be mentioned in this report concerning the delegated facilities. The analysis is expected to resume once a consistent basis is re-established at the conclusion of the DDS effort.

1.3.4 FAA/Industry Collaborative Efforts

The Production and Airworthiness Division, AIR200, has initiated several activities in collaboration with the aerospace industry and professional aerospace manufacturing organizations. The FY 1998 ACSEP analysis results were discussed at the April 1999 meeting between the FAA and the Manufacturing, Maintenance, & Repair Committee (MMRC) of the industry groups Aerospace Industries Association (AIA) and the General Aviation Manufacturers Association (GAMA). Based upon the analysis results, the MMRC agreed to form a team, in cooperation with the FAA, to attempt to formulate plans to reduce findings and observations. The team is composed of both FAA personnel and industry experts. They are examining the ACSEP criteria and system elements. Their goal is to identify and consolidate criteria that are redundant or mask other issues. Additionally, they are investigating whether any criteria need to be added to address any areas not currently addressed by the current criteria.

Two joint FAA and industry teams were previously established in FY 1998. Those two teams are focusing on supplier control and internal audit. The supplier control team is developing a plan to reduce findings and observations in supplier control processes. The internal audit team has published an industry best practice document on internal audit

quality programs (available on the Internet at http://www.faa.gov/avr/air/air200/Bestprac.htm). This document provides information that may be used to design and implement an internal quality audit program. This document also incorporates a section on corrective action that discusses the role of root cause corrective action in addressing quality system deficiencies. Although the document is targeted at production approval holders, the procedures and practices outlined in the document can be applied to all aerospace industry manufacturers.

1.3.5 Issued a Revision to Order 8100.7

Two significant changes to the order in FY 1999 were the removal of the instructions for completing FAA Form 8100-6 "Record of findings/observations" from Order 8100.7 and highlighting violations to 14 CFR part 21 § 21.3 as potential safety issues. Form 8100-6 is now used as a common form by a number of evaluations and audits to record the required and encountered conditions of any discovered noncompliance issues. The instructions for completing Form 8100-6 can now be found in Appendix 8 of Order 8120.2A "Production Approval and Surveillance Procedures." The moving of the instructions for Form 8100-6 into Order 8120.2A is an attempt to simplify and standardize the procedures for recording noncompliance issues.

The definition of a safety finding now specifically mentions violations of 14 CFR part 21 § 21.3 as a potential safety issue to be reviewed by the Principal Inspector (PI). This change to the definition was prompted by a proposal made to the ACSEP National Continuous Improvement Team (NCIT). The NCIT felt that violations of § 21.3 deserved special attention and should be considered as potential safety issues.

1.4 Overview of the ACSEP Activity

The transition from QASAR to ACSEP occurred in FY 1993. *Figure 1-1* shows the growth of the program from FY 1993 to FY 1999 (all facilities where an ACSEP evaluation was performed, including PPS facilities, are shown in the figure). The evaluation of delegated facilities began in FY 1998 after the release of Notice N8100.13, Aircraft Certification Systems Evaluation Program Criteria for Delegated Facilities.

From FY 1993 through FY 1998, the number of evaluations performed at production approval holders increased annually at an average of 24 percent. The growth of the program was facilitated by an increase in the number of qualified manufacturing, engineering, and flight test personnel fully trained to perform ACSEP evaluations. The reduction in the number of domestic ACSEP evaluations from FY 1998 to FY 1999 is a result of the policy changes discussed in *Section 1.3*. The dramatic reduction in evaluations at international facilities is because virtually all these facilities were suppliers to domestic production approval holders. Since suppliers were removed from the ACSEP

schedule, evaluations at international facilities were also removed from the schedule[1]. *Table 1-1* itemizes the population of various production approval holders[2].

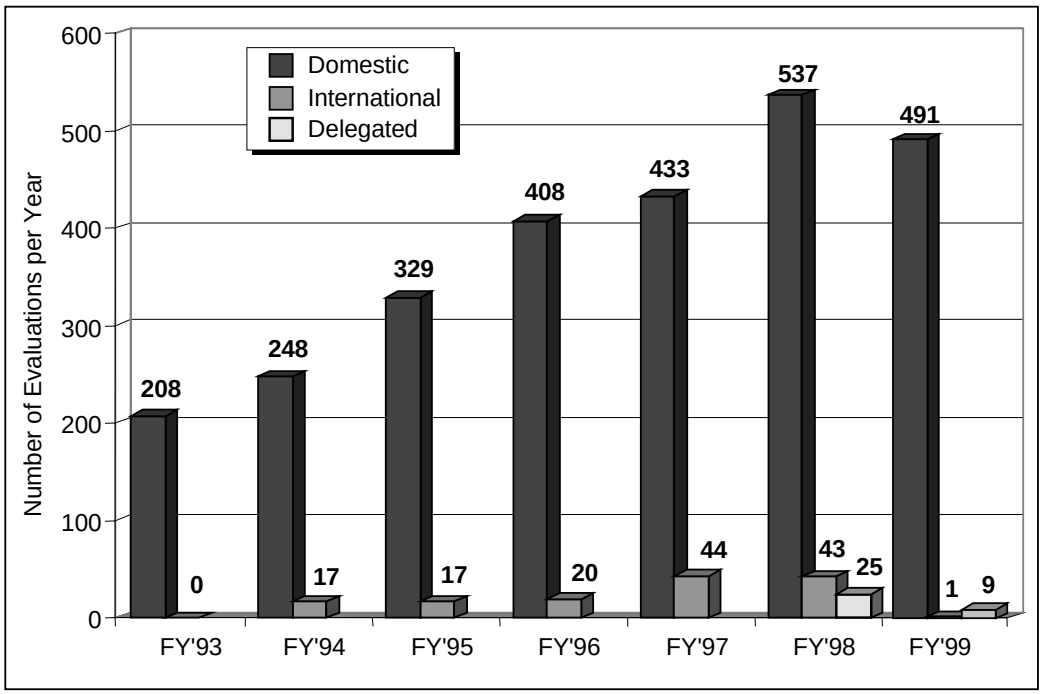

Figure 1-1.—Growth in annual ACSEP evaluations.

TABLE 1-1.—The population[3] of PAHs for fiscal years 1993 through 1999

Fiscal Year	Parts Manufacturer Approval (PMA)	Technical Standard Order (TSO) Authorization	Production Certificate[4] (PC)	Approved Production Inspection Systems (APIS)	Total number of Production Approval Holders (PAH)
1993	1,087	367	73	13	1,540
1994	1,140	379	74	14	1,607
1995	1,106	309	88	5	1,508
1996	1,413	342	70	13	1,838
1997	1,437	364	98	8	1,907
1998	1,211	307	98	5	1,621
1999	1,208	306	96	5	1,615

[1] Only one international facility was evaluated in FY 1999. Since any analysis based solely on this one evaluation would not be a representative sample of the international supplier base, it is not included in this report.

[2] Facilities with multiple production approvals are accounted for only once in accordance with the following order of precedence: PC (or PCEX), TSO, APIS, and PMA.

[3] This table is a compilation of data received from the individual directorates and is included in this report for reference only.

[4] Includes PC extensions.

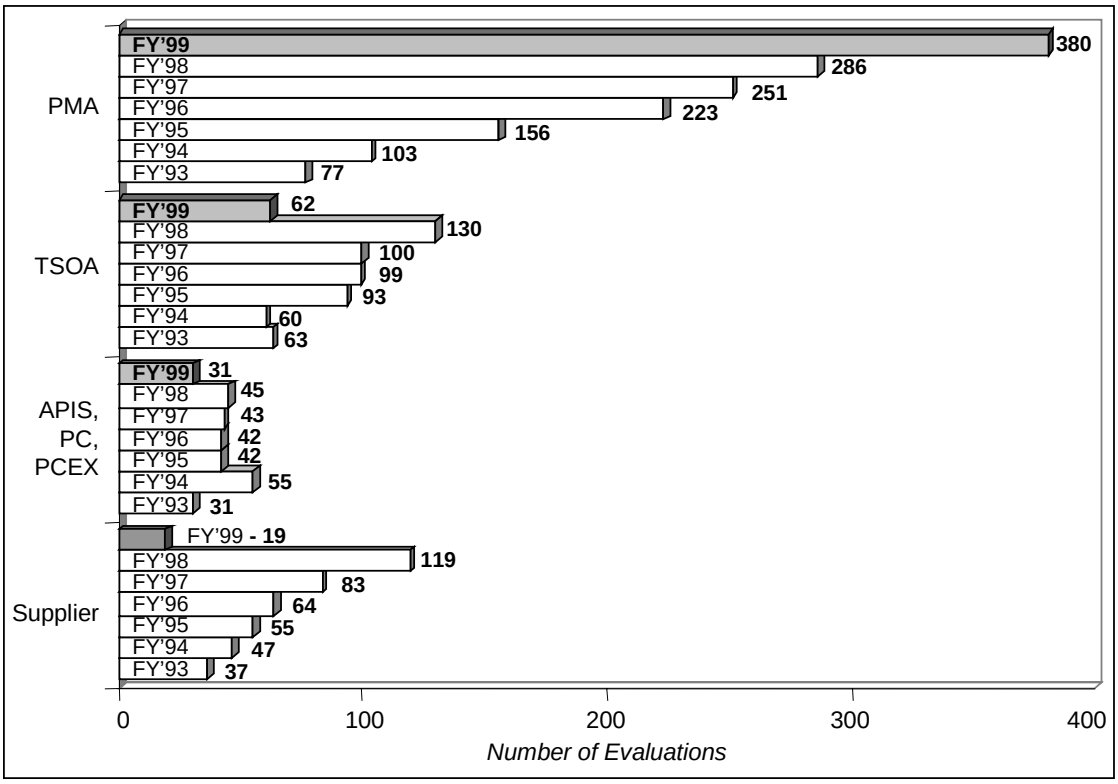

Figure 1-2.—Distribution of ACSEP evaluations at manufacturing facilities by facility type — domestic and international combined.

The growth in the number of manufacturing evaluations among the various facility types is presented in *Figure 1-2. Figure 1-2* shows the reduction in the number of supplier facilities evaluated in FY 1999 — the result of suppliers being removed from the ACSEP evaluation schedule. The reduction in the number of PC holders, PC extensions, APIS, and TSO authorizations is a direct result of Resource Targeting. The number of PMA holders increased to a number that was consistent with both the population of PMA facilities and current ACSEP policy. Any future increase or decrease in the number of PMA holders evaluated will reflect solely the growth or decline in the total population of PMA holders.

ACSEP evaluations were conducted by the Aircraft Certification Service's four directorates. *Figure 1-3* shows the distribution of all manufacturing evaluations among the four directorates.

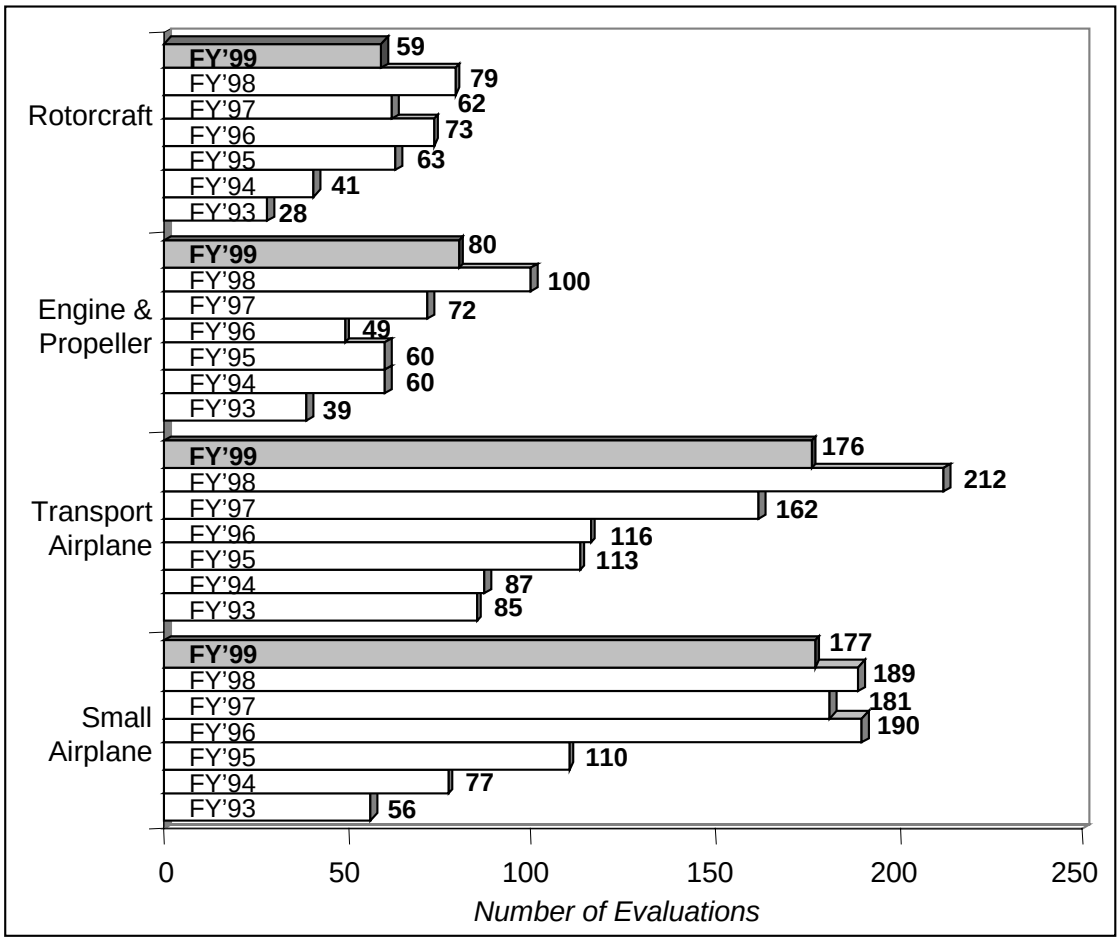

Figure 1-3.—Distribution of ACSEP evaluations at manufacturing facilities by directorate — domestic and international combined.

Table 1-2 lists the population of the various delegations. The distribution of the ACSEP evaluations among the various delegation types and among the various directorates is shown in *figures 1-4 and 1-5* respectively.

TABLE 1-2.—The population[5] of delegated facilities for fiscal 1999

Fiscal Year	Designated Alteration Station (DAS)	Special Federal Aviation Regulation No. 36 to CFR part 121 (SFAR-36)	Delegation Option Authorization (DOA)	Total number of Delegated Facilities
1998	31	24	6	61
1999	30	22	6	58

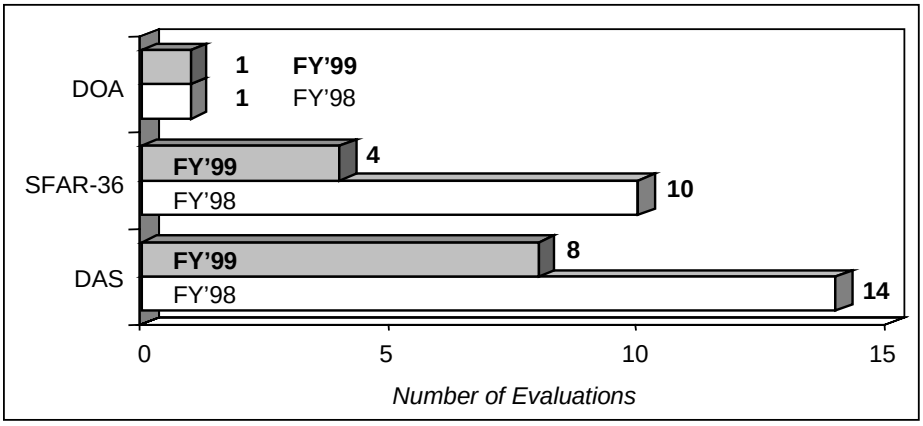

Figure 1-4.—Distribution of ACSEP evaluations at delegated facilities by delegation type.

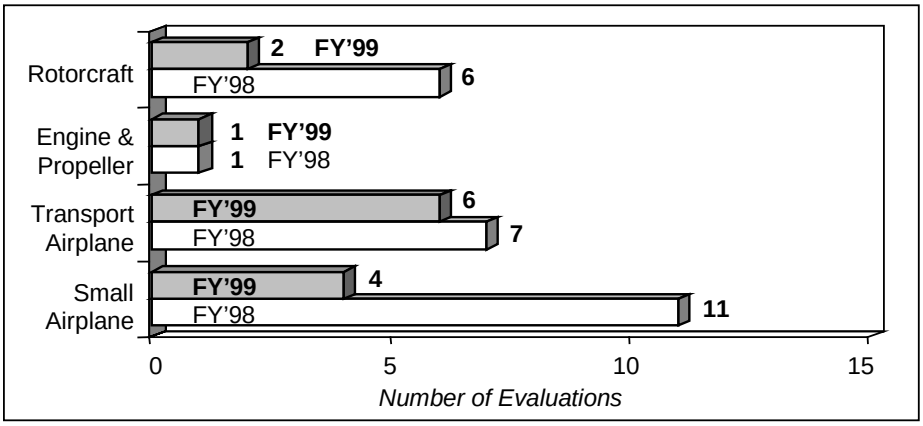

Figure 1-5.—Distribution of ACSEP evaluations at delegated facilities by directorate.

[5] This table is a compilation of data received from AIR-100 and is included in this report for reference only.

1.5 The Data Collected During an ACSEP Evaluation

The ACSEP was designed to determine if FAA production approval holders and delegated facilities are complying with the requirements of applicable Code of Federal Regulations (CFR) and the procedures established by these facilities to meet those requirements. It also surveys the application of standardized industry practices not required by the CFR to identify national trends that may require development of new or revised regulations, policy, or guidance. The elements of the evaluation are referred to as criteria. Data is collected on noncompliance, nonconformance, and applicability with respect to those criteria.

1.5.1 The Various Types of Issues

During an ACSEP evaluation, the actual operating practices of a facility are compared to the CFR, FAA-approved data, and the facility's internal procedures. Any inconsistency discovered (termed issue in this report) is classified and recorded. An issue is classified by its type and the system element under which it is noted. There are five issue types:

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Systemic Observation - an issue that is systemic in nature and is a noncompliance to facility procedures that are not FAA approved.

Isolated Observation - an issue that is isolated or nonsystemic in nature, i.e., isolated to a particular person and/or timeframe and does not represent a breakdown in the quality management system. For an issue to be categorized an isolated observation, it must also be an isolated noncompliance to a CFR or FAA-approved data (or a noncompliance with the procurement instrument when a facility is a supplier).

CFR-based Observation - the discovery of FAA-approved data that is inconsistent with the CFR.

For this report, systemic findings and systemic observations are combined into one category — systemic issues. In practice, a noncompliance/nonobservance of a procedure can be recorded as either a finding or a systemic observation based solely on whether the

procedure was FAA approved. The number and type of procedures that are FAA-approved varies widely among the various approval types. Additionally, the CFR requirements differ among the various approval types. In order to reduce bias, most of the analyses within this report pool finding and systemic observation data. Unless otherwise specified, all future references to "systemic issues" will relate to occurrences of both findings and systemic observations.

1.5.2 Issues are Classified into System Elements

The second form of classification of an issue is the system element under which it is discovered. In total, there are 17 system elements that represent a quality management system for a production approval holder:

- Organization and Responsibility
- Design Data Control
- Software Quality Assurance
- Manufacturing Processes
- Special Manufacturing Processes
- Statistical Quality Control (SQC)
- Tool and Gauge
- Testing
- Nondestructive Inspection
- Supplier Control
- Nonconforming Material
- Material Handling/Storage
- Airworthiness Determination
- FAA Reporting Requirements
- Internal Audit
- Global Production
- Manufacturing Maintenance Facility

There are 10 system elements that represent a quality management system for a delegated facility:

- Organization and Responsibility
- Design Data Approval
- Testing
- Airworthiness Certification
- Continued Airworthiness
- Project Management
- Design Change Approval
- Conformity Inspection
- FAA Notification
- Audit

1.5.3 And Further Classified into Criteria

Each system element is further divided into "criteria." The criteria were developed with extensive assistance from industry in order to fully represent the detailed areas within each of the system elements. A process also exists to identify potential new criteria should the existing criteria not address a particular functional area within a system element. The subclassification of issues into the detailed criteria allows the FAA to identify specific areas of concern and allows industry to focus corrective action on these specific areas of concern. For example, the supplier control system element is composed of 16 individual criteria. Specific areas of concern that may be identified include: the use of approved suppliers; periodic evaluations of suppliers; flowdown of applicable technical and quality requirements to suppliers; raw material verification; and others.

Through the use of detailed criteria and their relevant system elements, quality management systems can be evaluated in a consistent manner. Annually data is collected and analyzed for trends. In FY 1995, the data was baselined so that the effectiveness of any industry actions to address issues previously reported can be detected and measured.

2. Conclusions of the Data Analysis

Analysis of the FY 1999 ACSEP evaluation data supports the following conclusions:

- Two separate trends appear to be developing concerning safety findings. The first is the failure to report to the FAA failures, malfunctions, or defects. There were two safety findings reported in FY 1999 in this area and in both cases the FAA had ***never*** been notified of the malfunctions or defects on safety critical assemblies.

  The second and more significant trend is the discovery of insufficient inspection methods and plans to ensure that parts were inspected for conformity with FAA-approved design data. For two consecutive years (FY 1997 and FY 1998), a safety finding was reported in this area. What amplifies these two safety findings is that this is also the third most frequent area for nonsafety related issues.

- The majority of findings and observations are concentrated within a few system elements: manufacturing processes, supplier control, tool and gauge, design data control, nonconforming material, and special manufacturing processes (see *Section 3.2 – 3.4 and 3.6*). The issues are also concentrated within a few individual criteria (see *Section 3.7*). In fact, 94 percent of all issues were from the previously mentioned top six system elements. Additionally, two-thirds of all issues are reported in only 24 criteria.

- The larger the facility or the more complex the quality management system at the facility (the more parts and products produced, the more processes in place, the more complex the facility's controls, etc.), the higher the probability of findings and observations being recorded. Strong evidence of this relationship has been consistently observed for the last five years. Significant in-and-of-itself, understanding this relationship is imperative in the analysis of many other trends. See *Section 3.5* for additional information.

- Unlike the analyses results reported in previous years, the current analysis indicates that the approval types have different rates of compliance. TSO authorizations were 80 percent more likely to have issues than PC holders and 60 percent more likely to have issues than PMA holders. PC and PMA holders had similar compliance rates. *Section 3.5* provides a detailed discussion on these differences.

- Resource Targeting did not appear to predict which facilities would be more likely to have compliance issues. The weighting system currently used in the Resource Targeting program will need to be adjusted in order to improve its predictive capability. A detailed study scheduled for the latter part of FY 2000 will focus on how the safety factors used by Resource Targeting should be adjusted in order to reap the full benefits of the program (*Section 3.5.2*).

- The trend analysis shows almost universal downward trends in the number of facilities where findings and observations were reported (see *Section 3.7*). There has been a three percent annual drop in facilities reported having issues. Most of the system elements and criteria that have historically been the most troublesome have

shown marked improvement in reported noncompliance. The one exception is special manufacturing processes at PC holders (18 percent increase in reported issues in the last five years). *Figure 3-14* illustrates this lone upward trend.

- There were definite relationships between compliance and internal audit. Large facilities with internal audit programs were less likely to have findings and observations. There did not appear to be any relationship between internal audit and compliance at smaller facilities. However, facilities with systemic issues reported in their internal audit programs were 16 times more likely to have additional systemic issues than facilities that followed their established internal audit procedures. Simply implementing an internal audit program was not enough — it is imperative that a facility adheres to its internal audit program. *Section 3.9* provides a summary of this analysis.
- Industry, in past meetings, asked the FAA to study the specific problems associated with the numerous findings and observations reported in supplier control. The evaluation reports from facilities with past supplier control issues were extensively investigated. Some very definite trends emerged:
    - The issues were not supplier issues, but, rather the failure of production approval holders to comply with their established procedures and regulatory requirements for controlling their suppliers.
    - 90 percent of the issues fell into only a few key areas.
    - The various approval types have different issues.

        PC holders had issues with:

        - a general failure to flow down applicable technical and quality requirements to suppliers
        - performing tasks to unapproved or outdated procedures
        - failure to control the suppliers' design data

        PMA holders had issues with:

        - use of unqualified suppliers
        - failure to re-survey suppliers on schedule in order to determine their capability to meet requirements
        - inability to trace the physical properties of raw material

        TSO authorizations had issues with:

        - use of unqualified suppliers
        - failure to re-survey suppliers on schedule in order to determine their capability to meet requirements
        - performing tasks to unapproved or outdated procedures

3. Data Analysis — Manufacturing Facilities

3.1 Safety Related Findings

Of the 646 findings and observations recorded in FY 1999, two identified immediate safety concerns. Both of these safety findings were issued for failing to notify the FAA of failures, malfunctions, and defects (criteria 14C1) as required by 14 Code of Federal Regulations part 21 § 21.3, Reporting of Failures, Malfunctions, and Defects. In both findings, the FAA had ***never*** been notified of the malfunctions or defects on safety critical assemblies. Additionally, the malfunctions or defects had originally occurred more than a year prior to the ACSEP evaluations discovering them unreported to the FAA. This would suggest a systemic lack of notifying the FAA rather than an administrative delay to notification.

Since FY 1995, there have been 13 other non-safety findings reported for criteria 14C1. Of these previous 13 non-safety findings, the FAA had eventually been notified in 11 of the cases, but had not been notified in the timeframe required by the CFR. The other two cases dealt with the FAA never being notified; however, the Principal Inspectors for the facilities did not deem the issue to be of a safety critical nature.

The occurrence of two safety findings for the same criteria within the same year should be considered a significant event. There does not appear to be an increasing trend in the general noncompliance with CFR § 21.3. However, there does appear to be a shift from delaying notification to complete lack of notification (refer to *figure 3-1*).

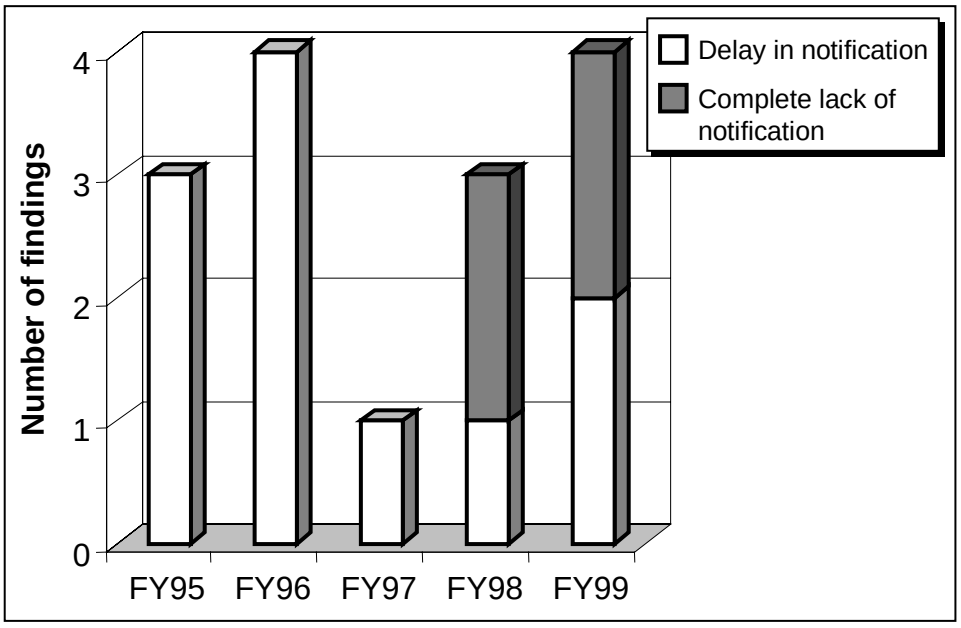

Figure 3-1.—Trend for failing to notify the FAA of failures, malfunctions, and defects.

There was a modification to the definition of a safety finding that specifically highlighted noncompliance with CFR § 21.3 as a potential safety issue. This revision to the order may have heightened awareness of the issue and may be partly responsible for the reporting of the two safety findings. However, the modification to the definition of a safety finding would not explain the shift from delay in notification to complete lack of notification. Notwithstanding the modification to the definition, the two safety findings for failing to notify the FAA of failures, malfunctions, and defects is a significant event.

There also appears to be a safety finding trend in another area: failure of inspection methods and plans to ensure conformance to FAA-approved design data (Criteria 4Q1). A safety finding in this area has been recorded for two consecutive years (FY 1997 and FY 1998). Criteria 4Q1 is also the third most frequently reported issue of noncompliance at production approval holders. Coupled with the frequency that criteria 4Q1 is reported, the two consecutive years of reported safety findings is considered significant.

Table 3-1 summarizes the nine safety findings reported at production approval holders since FY 1995. The criteria are ordered by relative significance (based on the number of times a safety finding was reported and the frequency the criteria had non-safety findings and observations reported).

TABLE 3-1. —Safety findings reported at production approval holders since FY 1995

Criteria	Description	Number of reported safety findings	Year(s) that findings were reported	Is the criteria reported at a high frequency?
4Q1	Inspection methods and plans	2	98 & 97	Yes
14C1	Failure reporting	2	99	No
4P4	Work instructions control manufacturing processes	1	98	Yes
11Q1	Control of nonconforming product	1	98	Borderline
12Q5	Identification of age control products	1	97	Borderline
4Q12	Completion of all inspections and tests	1	98	Borderline
13Q2	Airworthiness certificates/special flight permits	1	98	No

3.2 Systemic Issues

There were 512 systemic issues reported in FY 1999. At least one systemic issue was recorded at 39 percent of the production approval holders evaluated in FY 1999. Of all of the systemic issues recorded, 78 percent were recorded within only six of the system elements. These six system elements are displayed in *figure 3-2.* It should also be noted, that of those facilities that had systemic issues reported, 94 percent had at least one of the top six issues displayed in *figure 3-2.* The issues reported within these six system elements are considered significant and pervasive throughout the industry.

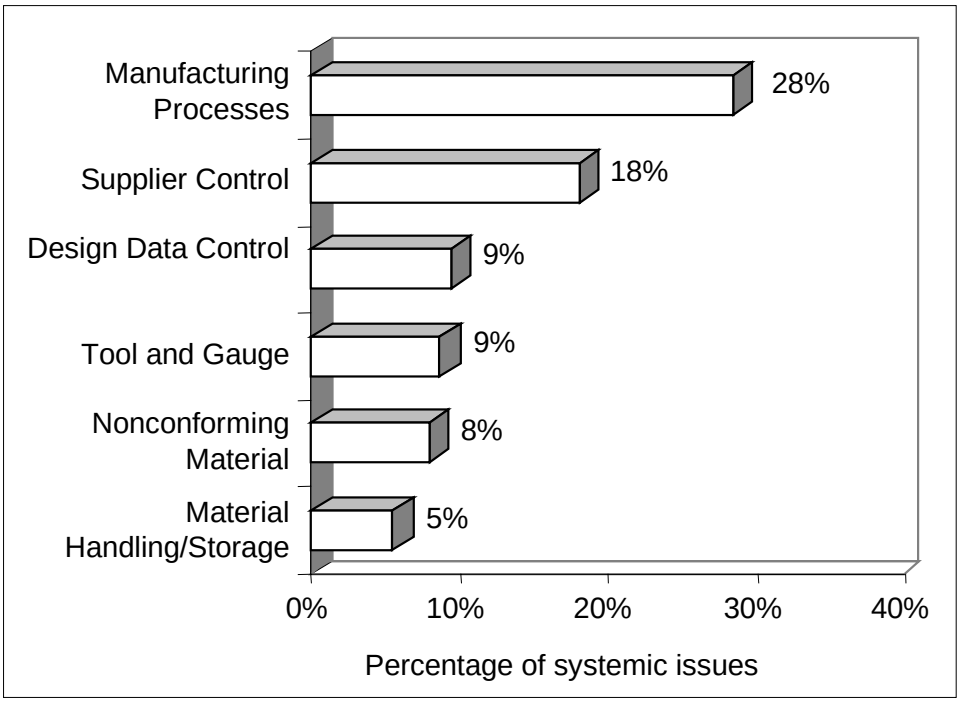

Figure 3-2.— Systemic issues – all facility types.

3.3 Isolated and Systemic Issues

There appears to be similarity between the distribution of systemic issues and the distribution of isolated issues. The two different types of issues are defined as:

Systemic issue	• System breakdown • Pervasive • Repeatable • Safety related
Isolated issue	• Not a system breakdown • Confined • Random event

Figure 3-3 presents the frequency distribution of isolated observations at the system element level. The six system elements displayed in *figure 3-3* account for 78 percent of all isolated issues reported for the fiscal year. The distribution of isolated observations is similar to the distribution of systemic issues (refer to *figure 3-2*). *Table 3-2* compares the top tenth percentile of isolated observations at the criteria level to those criteria with systemic issues also within the top tenth percentile. Half of the top isolated issues are also the top systemic issues. The correlation between isolated and systemic issues has been seen for the last five years. This apparent similarity between the frequency distributions at both the system element and criteria level supports a conclusion that they are somehow related.

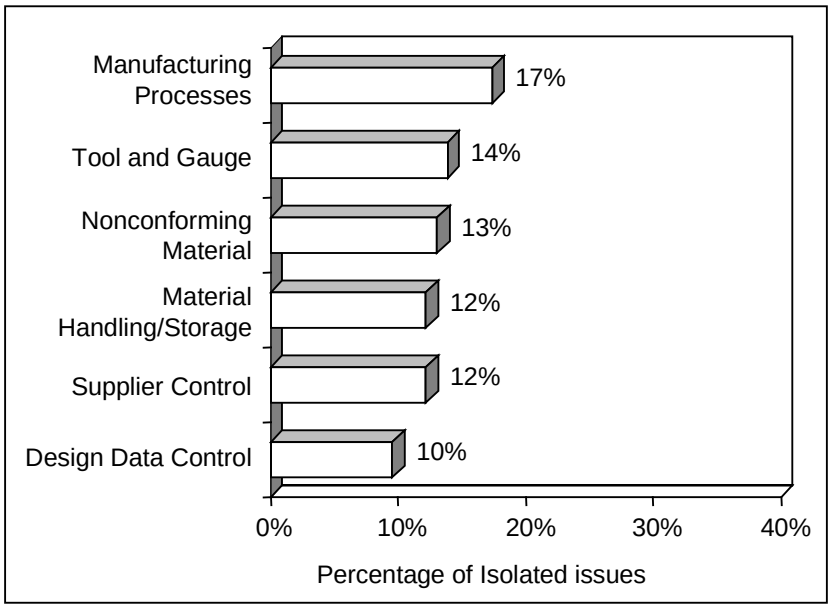

Figure 3-3.— Isolated issues – all facility types.

TABLE 3-2.—Top ten percentile of isolated issues compared to the top ten percentile of systemic issues

Criteria	Description	Rank of Isolated Observation	Systemic Issues
11Q1	Control of nonconforming products	1	✘
7Q1	Approval/inspection of tools and gauges	2	
4P9	Completed part/product identification	3	✘
12Q5	Identification of age control parts	4	
2E1	Design change approval	5	
10Q10	Receiving inspection	6	✘
✘ = within top ten percentile of systemic issues			

Assuming the correlation exists, and there is strong evidence from the FY 1995 through the FY 1999 data to suggest that it does, there are two probable causes for this apparent similarity between systemic and isolated issues. One theory is that those areas that are more prone to systemic issues are also more likely to have isolated issues. Another theory is that a large portion of the isolated issues are indications of larger systemic issues. In other words, given more investigation, sufficient evidence could have been uncovered to lead the evaluation team to determine the issues to be symptoms of latent systemic breakdowns in the quality management system, thereby warranting them to be reclassified as systemic issues.

3.4 CFR-Based Observations

There were only 19 CFR-based observations reported in FY 1999. CFR-based observations have been steadily declining for the last five years at a rate of about 22 percent per year. CFR-based observations have declined despite an average 24 percent annual increase in the number of facilities evaluated. *Table 3-3* lists those system elements where the CFR-based observations were reported. Further discussion on the trends seen over the last five years is contained in *Section 3.8.3*. A detailed listing of CFR-based observations and the specific criteria they were reported under is located in *Appendix C*.

TABLE 3-3.—CFR-based observations

Domestic	Number of CFR-based observations reported
Manufacturing Processes	4
Special Manufacturing Processes	4
Supplier Control	3
Design Data Control	2
Organization & Responsibility	1
Software Quality Assurance	1
Statistical Quality Control (SQC)	1
Nonconforming Material	1
Airworthiness Determination	1
FAA Reporting Requirements	1

3.5 Comparison of Facility Types

This section compares the occurrence of issues among the various facility types. However, what must be first considered is any effect facility size and system complexity may have on the results of this analysis. Additionally, any effect the implementation of Resource Targeting may have on the analysis must also be considered. The next two subsections discuss the effects that system complexity and Resource Targeting have on the ACSEP evaluation results. The subsequent subsections discuss the particular results for systemic and isolated issues.

In order to ensure a fair comparison of the various approval types, the FY 1998 and FY 1999 data were pooled[6] and analyzed as one sample. This was done in order to remove a biannual cyclical bias. This biannual cycle can be readily seen in the trend analysis presented in *section 3.8.1*. Steps are taken to ensure that there was no double accounting of facilities evaluated in two consecutive years.

One additional note concerning the analysis results within this section. Comparisons made of the various approval types are calculated with a 90 percent confidence interval. The 90 percent confidence interval was chosen in order to highlight any differences as soon as possible. *Appendix E* has a more detailed explanation of the use of a 90 percent confidence interval.

[6] See *Appendix E* for the justification for pooling the data.

3.5.1 Complexity of Systems

Both the number of systemic and isolated issues and the probability of a facility having such issues correlate very strongly to the complexity of the systems in use at the facilities being evaluated. The factors that define system complexity are:

- Facility size
- Number of employees
- Production rate
- Number of procedures
- Number of production certificates
- Number of processes
- Special/complex processes

The probability of a facility having processes noncompliant with established policies or procedures appears to increase proportionately with system complexity (see *Figure 3-4*). It should be noted, however, that a facility's complexity (or simplicity) does not guarantee the presence or absence of noncompliances. There were several examples of fully compliant large, complex systems. Conversely, there are several examples of small, simple systems with several noncompliances. Analysis indicates that the number of evaluators present during an ACSEP evaluation is a common factor that can be used to predict this phenomenon. The number of evaluators was used to normalize the data for comparisons among the various facilities. This normalization removes the apparent bias produced when comparing, for example, a very large, high-technology PC holder with a small, low-technology PMA. The specific results of the normalized comparisons among the various facility types are discussed in further detail in the following subsections.

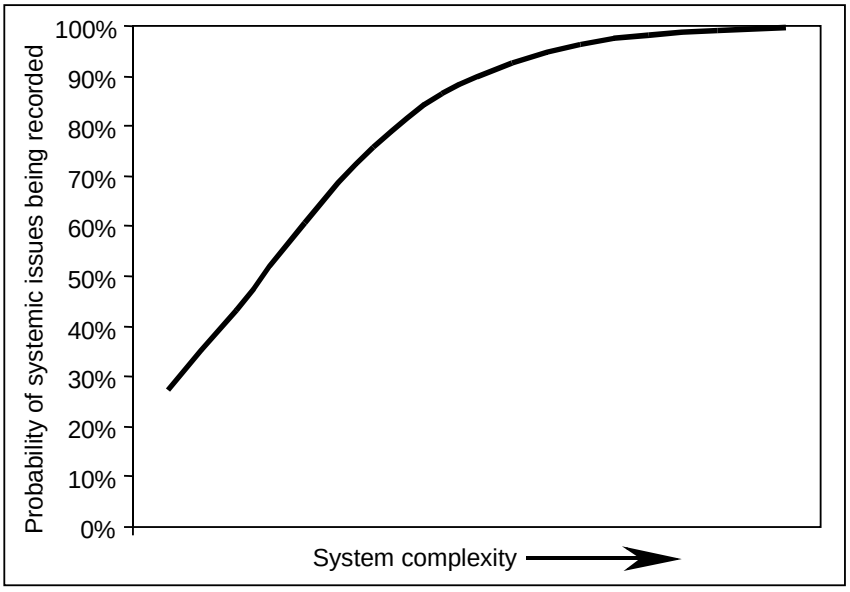

Figure 3-4.— Systemic issues and system complexity are related.

All further analyses comparing different approval holders will control for the number of evaluators[7] present at the evaluation, i.e., system complexity.

3.5.2 Resource Targeting

Resource Targeting is a method of prioritizing ACSEP evaluations based upon assessment of the potential safety impact of individual production approval holders. Its objective is to better allocate resources according to an assessment of risk factors. A systematic summarization of these risk factors for each PAH facility would then be used to determine the frequency at which the facility is to be evaluated. Each facility would be classified into one of four Resource Targeting groups (RT groups).

Resource Targeting replaced the previous system of establishing an evaluation schedule based solely upon approval type. Prior to Resource Targeting, all PC, TSO, and APIS authorizations were evaluated every 24 months. The frequency at which PMA holders were evaluated was dependant upon whether they produced any priority parts: 24 months if they produced priority parts, and 48 months if they did not produce priority parts.

Once Resource Targeting was implemented, each facility was evaluated on 21 safety factors along with the criticality of the parts produced by that facility. These safety factors and part criticality are weighted and summarized into two aggregate factors: system strength and inherent risk. The collective score of the two aggregate factors determines which of the four RT groups is assigned to the facility. The RT group determines the frequency at which a facility is evaluated:

RT group I:	evaluated every 16 to 24 months
RT group II:	evaluated every 24 to 36 months
RT group III and IV:	evaluated every 32 to 48 months

3.5.2.1 Potential impact of Resource Targeting on the analysis

The implementation of Resource Targeting changes the selection method for choosing a sample of facilities to be analyzed. Such a change to the basic sample selection method has a potential of impacting the analysis results. A sample plan was developed that would ensure that any facility within each of the RT groups had an equal chance to be selected. Data analyzed from each RT group could then be analyzed to determine the extent of any impact, if any, Resource Targeting had on the analysis results. When comparing trend data from previous years (where Resource Targeting was not employed) to FY 1999 (where Resource Targeting was employed), adjustments could then be made in order to compensate for any impact that Resource Targeting might induce in the FY 1999 analysis data.

[7] The total evaluator-hours spent evaluating the facility was also studied. Evaluator-hours, however, weakened the model. The number of evaluators alone was the most reliable parameter found.

3.5.2.2 Actual impact of Resource Targeting on the analysis

The FY 1999 data was analyzed several different ways in order to determine if there was any relationship between compliance issues and the RT groups. In all cases, the analyses were controlled for system complexity; discussed in the previous section as having a very strong relationship to compliance issues.

Resource Targeting did not appear to predict which facilities would be more likely to have compliance issues. The analysis indicated that, *given system complexity*, no significant relationship exists between the various RT groups and compliance issues. This infers that RT groups have no appreciable predictive capability in the model. Therefore, RT groups were left out of the analysis. Additionally, FY 1999 data can be compared with previous years' data without any adjustment to account for Resource Targeting.

It appears that the current weights assigned of the various risk factors do not provide adequate predictive capability of a facility having compliance issues reported. A detailed analysis is underway to determine if different weights for the risk factors would be more effective in predicting compliance issues.

3.5.3 Systemic Issues

Analysis indicates that the occurrence of systemic issues were relatively similar between PC and PMA holders. TSO authorizations, however, had a higher probability of systemic issues than either PC or PMA holders. The odds of systemic issues being reported at TSO authorizations were 80 percent higher than at PC holders and 60 percent higher than at PMA holders. *Figure 3-5* shows these differences. There is only marginally significant evidence supporting the difference between PC and TSO facilities. However, there is very strong evidence supporting the difference between PMA and TSO facilities. *Figure 3-6* presents the same data, but with error bars to highlight the variance in the data. For ease of comparison, the median system complexity factor of two evaluators per evaluation was used.

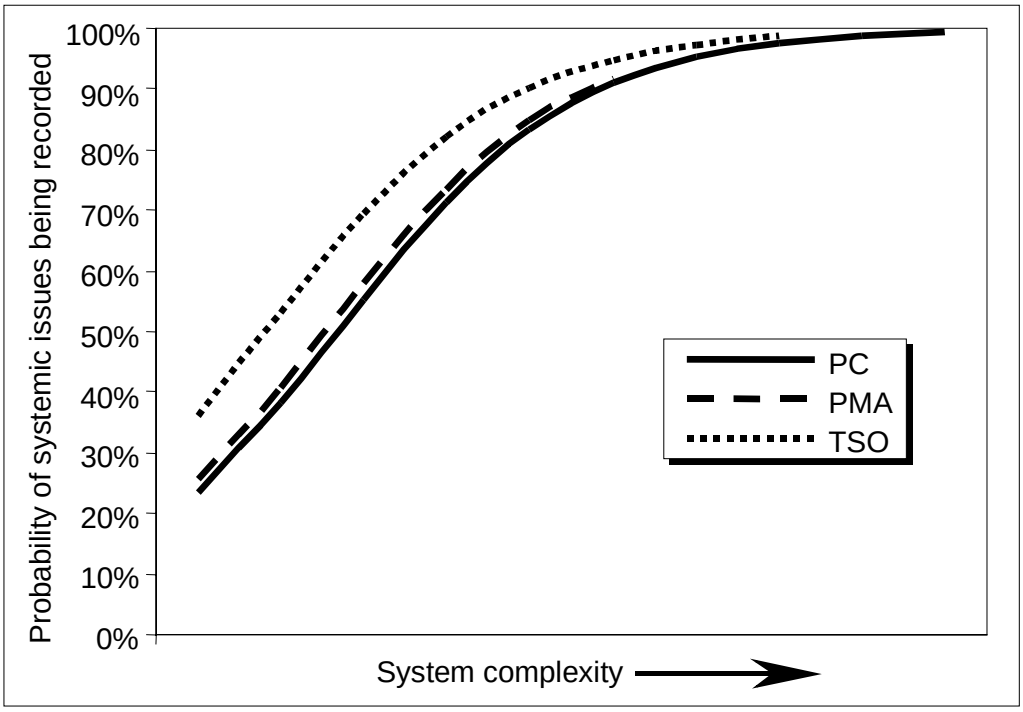

Figure 3-5.— Comparing systemic issues for the various approval holders.

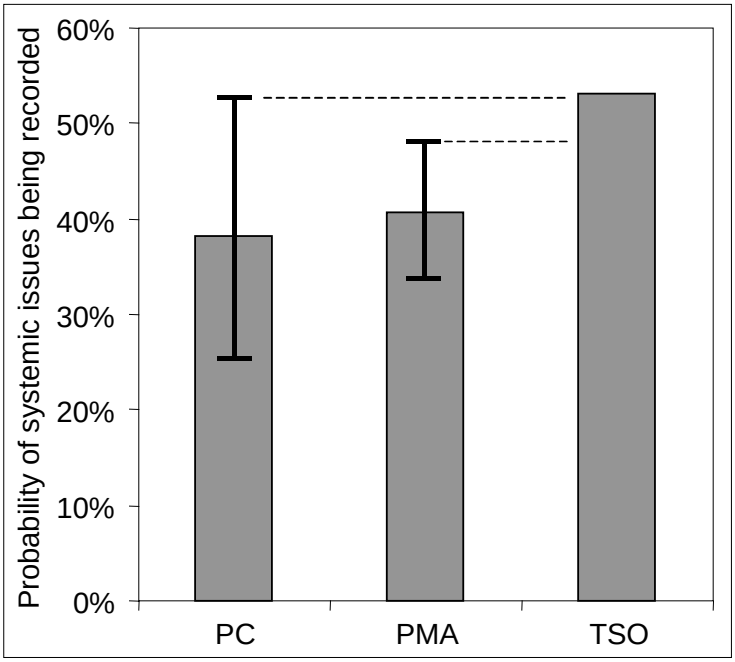

Figure 3-6.— Comparing systemic issues for the various approval holders — 90 percent confidence interval.

These analysis results are consistent with those reported in the FY 1996, FY 1997, and FY 1998 reports. TSO authorizations have had a higher probability of systemic issues for the last four years. The trend analysis discussed in Section 3.7 offers some insight into why TSO authorizations appear to have more systemic issues reported than the other approval holders.

3.5.4 Isolated Observations

The same type of analysis as presented in the previous subsection was also performed for isolated observations. There is extremely strong evidence that TSO authorizations had a higher probability of isolated issues than PMA holders. The odds of a TSO authorization having isolated observations are almost two and one-half times those of a PMA holder. From *figure 3-7* the difference between TSO authorizations and PMA holders is evident.

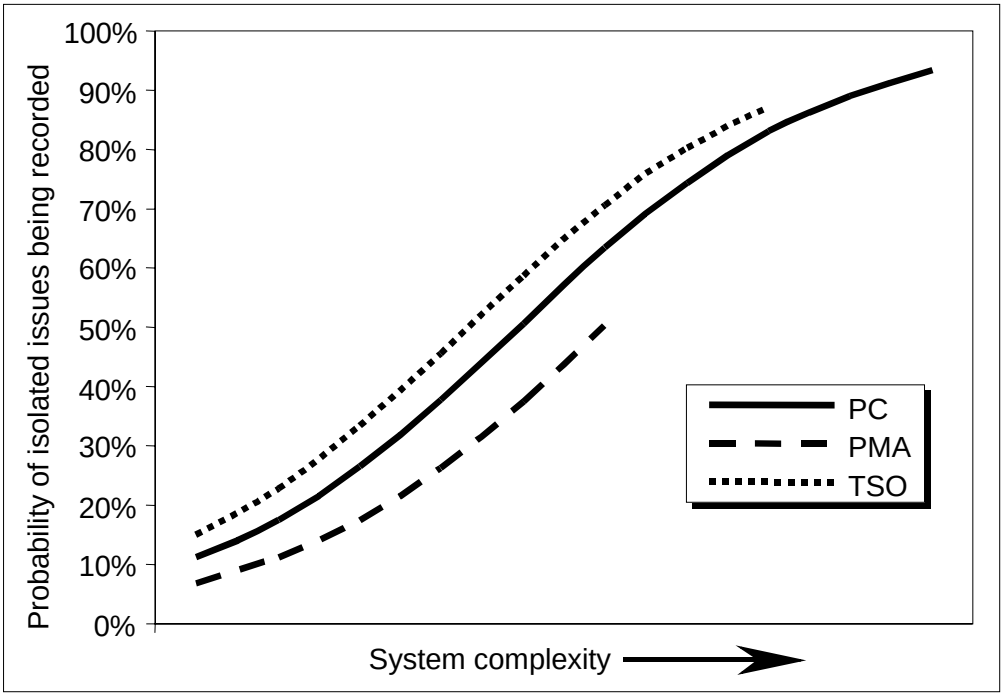

Figure 3-7.— Comparing isolated issues for the various approval holders.

The probability of isolated issues for PC holders is halfway between TSO authorizations and PMA holders. The sample error associated with PC holders, however, does not provide an estimate with enough precision to determine whether the difference between PC holders and either TSO authorizations or PMA holders is significant. *Figure 3-8* presents the same data as *figure 3-7*, but with error bars to highlight the variance in the data[8]. For ease of comparison, the median system complexity factor of two evaluators per evaluation was used.

[8] See *Appendix E* for an explanation of the use of a 90 percent confidence interval.

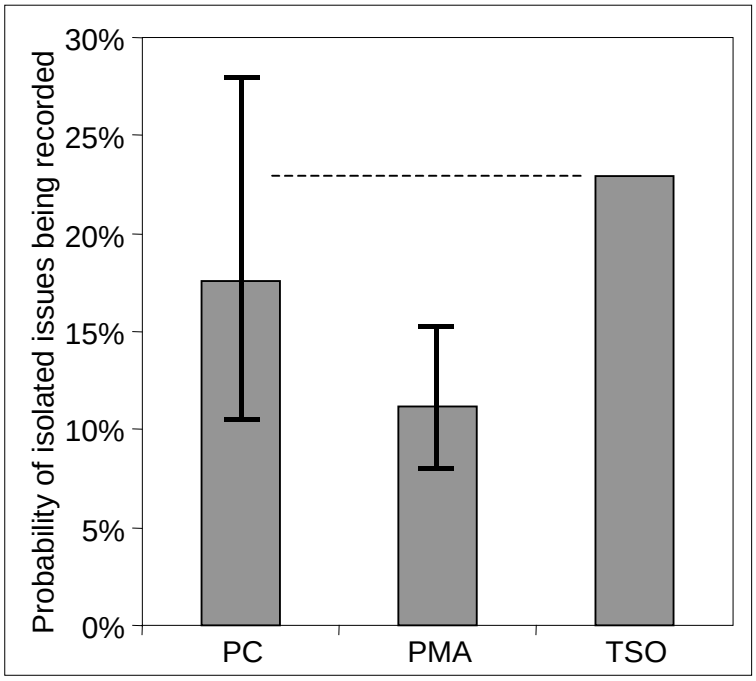

Figure 3-8.— Comparing isolated issues for the various approval holders — 90 percent confidence interval.

These analysis results are consistent with those reported in the FY 1998 report. The trend analysis discussed in *Section 3.7* offers some insight into why TSO authorizations appear to have more isolated issues reported.

3.5.5 CFR-based Observations

There were only 19 CFR-based observations reported in FY 1999. There were too few observations to compare the various approval types. *Section 3.7* has a five-year trend of CFR-based observation that provides insight into how the various approval types compare.

3.6 System Element Issues

3.6.1 Similarity Among Approval Types

The detailed analysis reveals striking similarities in the order in which the facilities have systemic issues within the system elements. *Figures 3-9 through 3-12* show the most prevalent issues for each of the approval types. *Figure 3-13* shows the most prevalent issues for all of the approval types combined. It is apparent from this analysis that the results for all of the approval types combined is similar to the results for any individual approval type alone. *Table 3-4* summarizes the data contained in the figures by comparing the most prevalent issues among the various facility types.

Please note that direct comparison of the approval types cannot be done with these charts. As revealed in the previous section, the proportion of facilities with systemic issues is strongly related to system complexity. Because there are significant differences in system complexity among the various approval types, these charts cannot be used to compare compliance between approval types.

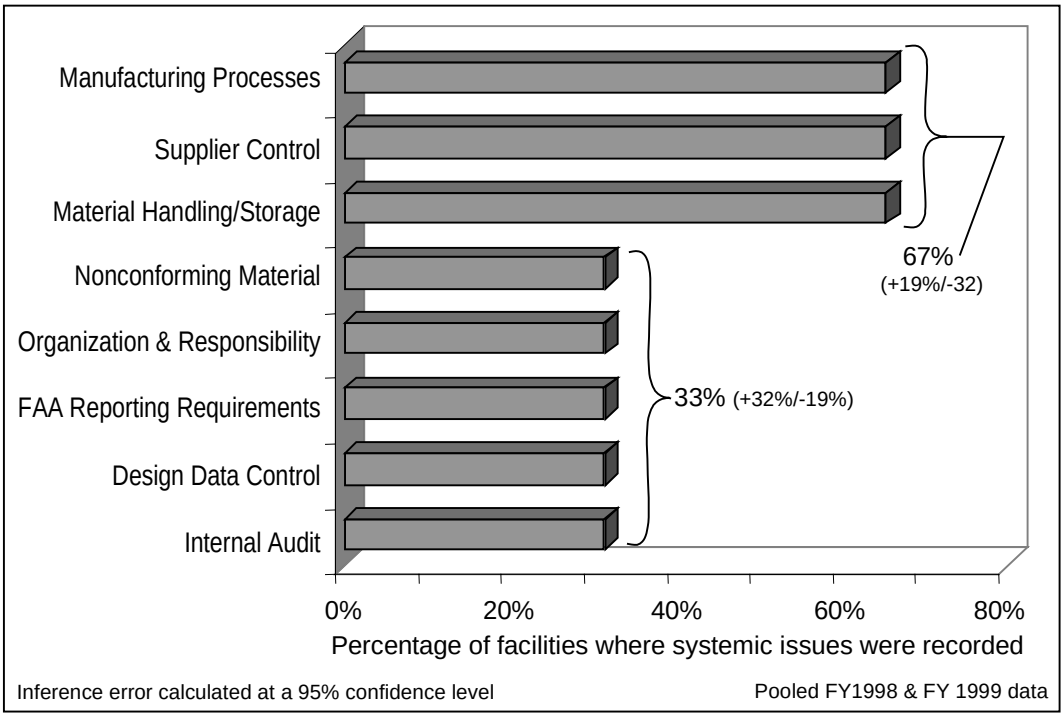

Figure 3-9.—Systemic issues – APIS[9] *holders.*

[9] The APIS data is shown with FY 1998 and FY 1999 pooled. No facility was evaluated more than once during this period. One facility was evaluated in FY 1998 and two in FY 1999. The apparently large inferential errors are due to the small number of facilities evaluated. However, the pattern of compliance rates still appears to mirror that of the rest of the industry. See the notes in the beginning of this section and *Appendix E* for an explanation of inferential error and its application.

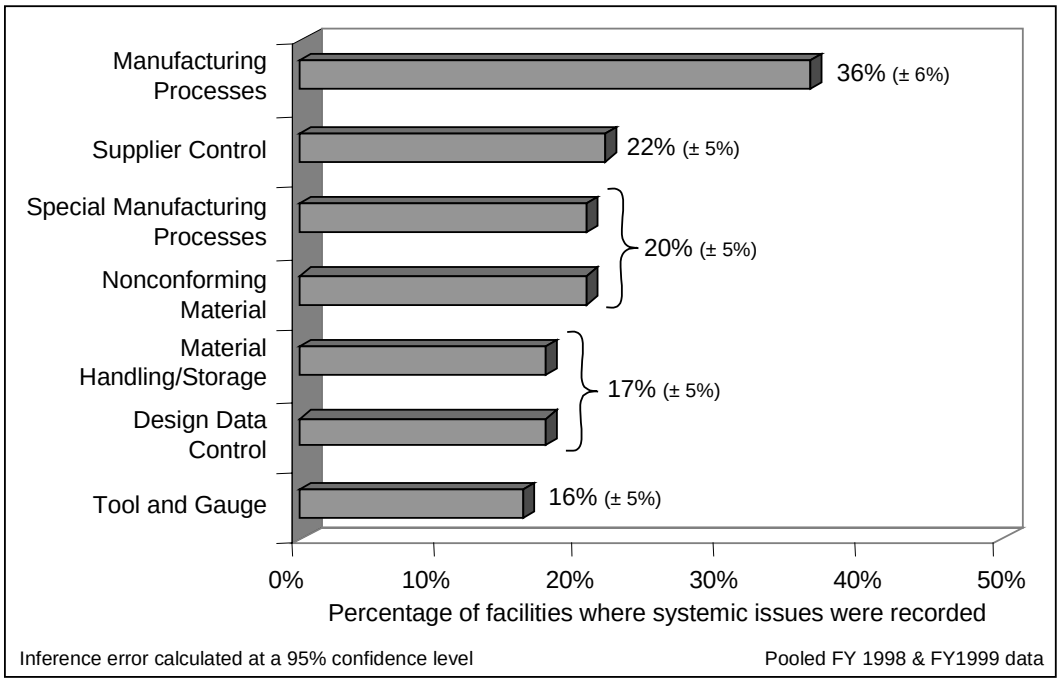

Figure 3-10.—Systemic issues – PC holders.

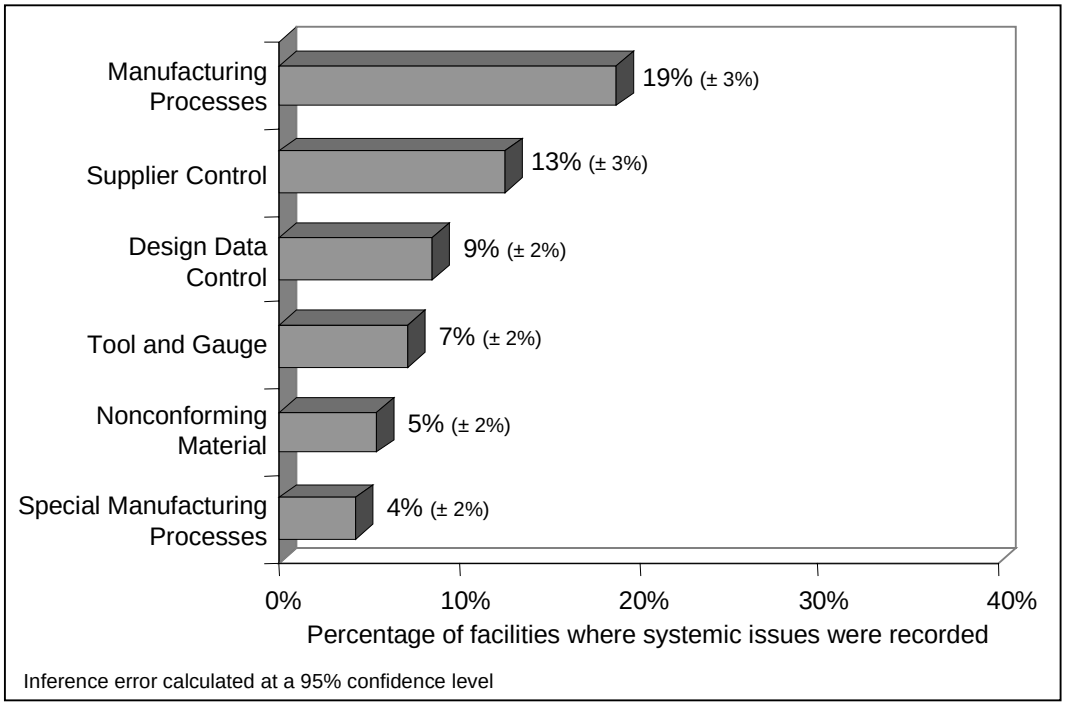

Figure 3-11.—Systemic issues – PMA holders.

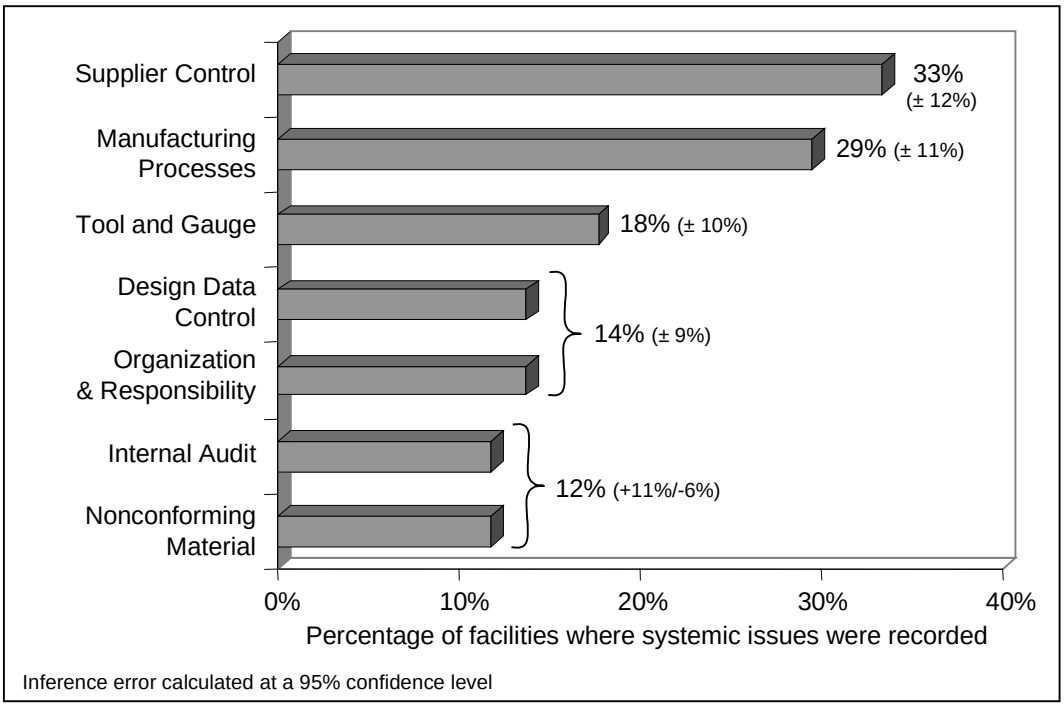

Figure 3-12.—Systemic issues – TSO authorization holders.

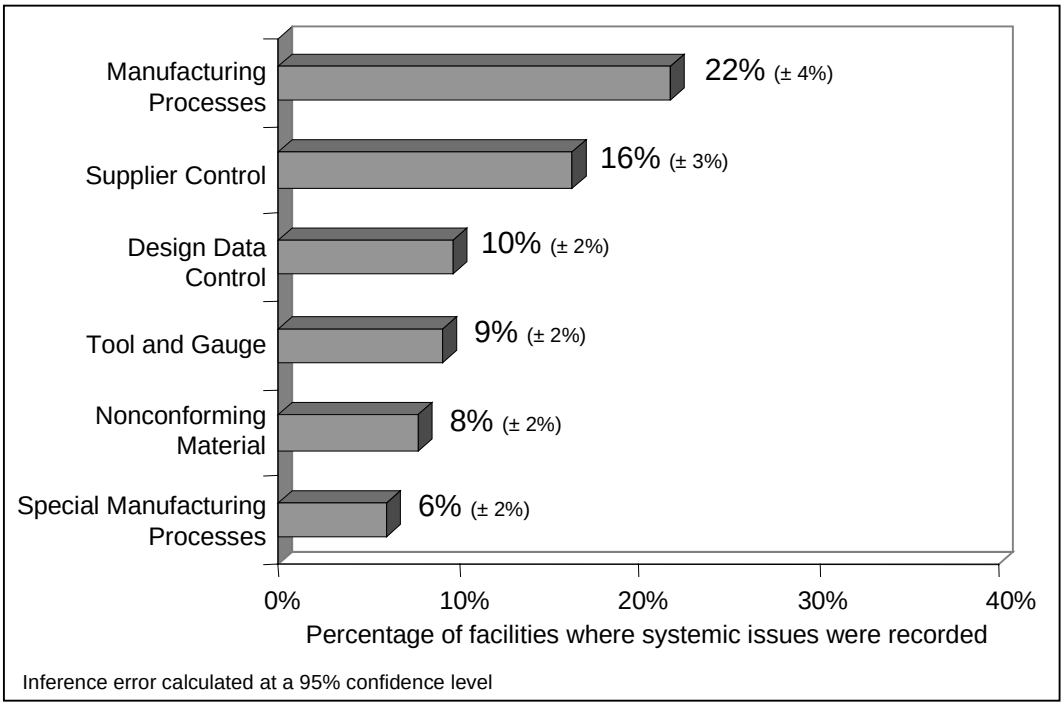

Figure 3-13.—Systemic issues – all approval types.

TABLE 3-4.—Summary of the most prevalent systemic issues

System Element	APIS	PC	PMA	TSO
Manufacturing Processes	✘	✘	✘	✘
Supplier Control	✘	✘	✘	✘
Design Data Control	✘	✘	✘	✘
Tool & Gauge			✘	✘
Nonconforming Material	✘	✘	✘	✘ *
Material Handling/Storage	✘	✘		✘
Special Manufacturing Processes		✘	✘	
Internal Audit	✘			✘ *

Leading issues for industry

✘ = One of the top six systemic issues

* = Tied

A five-year comparison of the most frequently cited system elements with systemic issues (*see Table 3-5*) indicates that there have been only minor variations in the order of occurrence at the system element level. The various approval holders appear to have similar key issues. With the exception of some minor shifting in position, the top issues have remained the top issues over the five years. A noteworthy exception is special manufacturing processes performed at PC holders. PC holders had a moderately higher proportion of facilities with systemic issues reported against their special manufacturing processes than the other approval types. In recent years, this system element has increased at PC holders by 18 percent (*figure 3-14*).

TABLE 3-5.—Most frequently cited system elements with systemic issues – FY 1995 to FY 1999

	Annual System Element Rank				
	FY 1995	**FY 1996**	**FY 1997**	**FY 1998**	**FY 1999**
ALL APPROVAL TYPES					
Manufacturing Process	1	1	1	1	1
Supplier Control	2	2	2	2	2
Design Data Control	3	4	4	3	3
Tool and Gauge	4	3	3	3	4
Nonconforming Material	4	5	6	5	5
Material Handling/Storage	6	6	4	5	6
PC					
Manufacturing Process	1	2	1	1	1
Supplier Control	2	3	2	3	2
Special Manufacturing Processes	12	4	4	3	3
Nonconforming Material	4	8	6	3	3
Tool and Gauge	3	1	3	8	5
Design Data Control	4	5	6	3	6
Material Handling/Storage	4	8	4	2	8
PMA					
Manufacturing Process	1	2	1	1	1
Supplier Control	2	1	2	2	2
Design Data Control	3	4	5	3	3
Tool and Gauge	6	4	3	3	4
Nonconforming Material	4	3	4	5	5
TSO					
Supplier Control	1	2	2	2	1
Manufacturing Process	1	1	1	1	2
Tool and Gauge	6	4	3	4	3
Design Data Control	3	3	4	4	4
Nonconforming Material	4	6	5	4	5
Material Handling and Storage	6	5	8	3	5

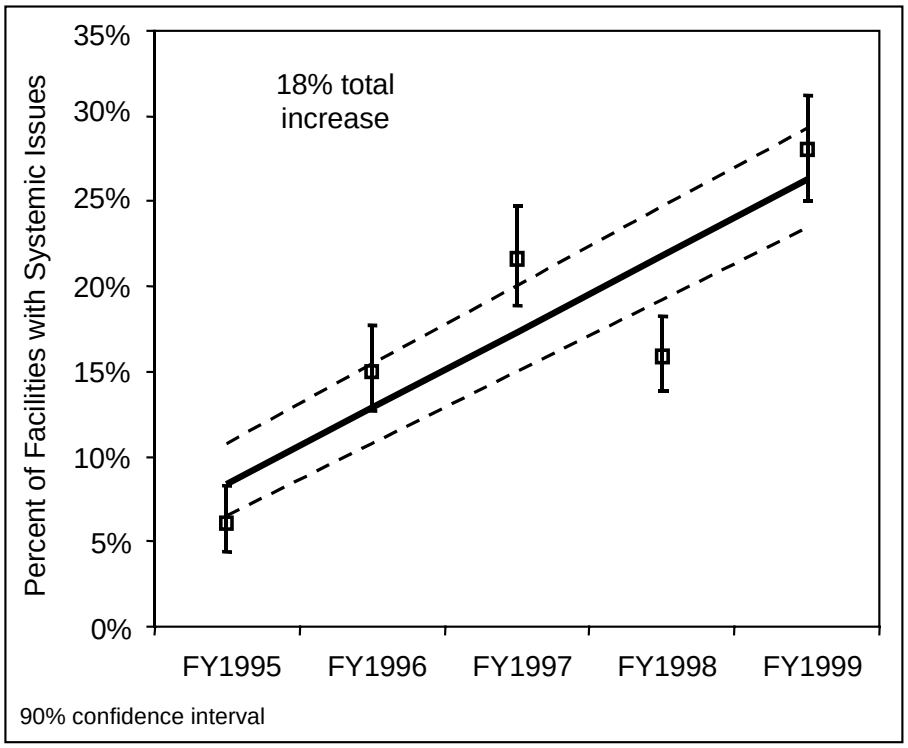

Figure 3-14.—Increase in special manufacturing issues at PC holders.

3.6.2 Differences Between the Approval Types

The previous subsection states that the approval types appear to have issues in the same system elements. Overall, this appears to be the case. The charts in the previous section present the proportion of all facilities that had issues. However, not all of the system elements are applicable to all facilities. An extreme example is the system element software quality assurance. Only eight percent of all facilities have software quality assurance systems. Overall, the number of facilities with systemic issues in this system element is small — only one percent of all facilities. However, of those facilities that have a software quality assurance system, nine percent had systemic issues reported. Whereas software quality assurance is not a significant area for issues overall, it is very significant for those few facilities where that system element applies. To gain a full understanding of the issues that affect the industry, we must look not only at the proportion of facilities overall that have issues, but also at the extent to which the system elements apply to industry.

Additionally, the various system elements do not equally apply to all of the approval types. For this reason, we will examine each of the approval types individually. The following table indicates where there may be some additional areas of concern that do not reveal themselves unless system element applicability is considered. In each case, the issues reported are not among the most prominent for industry as a whole. Should any of

the system elements listed apply to a larger number of facilities in the future, those system elements would quickly become some of the most prominent trouble areas.

Approval Type	System element	What proportion of facilities do the system elements apply?	What proportion of facilities where the system element applied had issues reported?
PC Holders	▪ Software Quality Assurance	23%	13%
PMA Holders	▪ Special Manufacturing Processes	40%	11%
	▪ Nondestructive Inspection (NDI)	13%	9%
	▪ Manufacturing Maintenance Facility	9%	7%
TSO Authorizations	▪ Special Manufacturing Processes	45%	17%
	▪ Software Quality Assurance	16%	25%

3.7 Analysis of Evaluation Criteria

The following subsections contain lists of the most significant criteria issues at any given facility type. This data can be used by industry to focus corrective action and by the FAA for resource allocation initiatives. The data is presented in three forms: a view of industry as a whole listed by type of issue — systemic or isolated; a focus on individual approval types in which systemic issues are separated by approval type; and a summary of comparisons among the approval types. For clarity, only the top issues are reported in these subsections; however, a full listing of this data can be found in *Appendix C*.

Many of the criteria that are the most prevalent for FY 1999 were also the most prevalent issues reported in the past. *Tables 3-5 and 3-7* present comparisons of the most prevalent criteria with which systemic and isolated issues occurred over the five-year period. The comparisons are done at the industry level only, i.e., with all facility types combined. With 228 different criteria from which to categorize the various findings and observations, a dilution effect occurs as the data is compared at the criteria level. Dividing the findings and observations still further into facility types reduces their occurrence within the individual criteria to a level too low with which to make reliable comparisons. The lowest level these types of comparisons can be reliably made is at the industry level. A five-year comparison of CFR-based observations is not presented due to their rarity — making such a comparison is unrealistic.

3.7.1 A View of Industry

This subsection lists the most prevalent criteria issues within the industry as a whole. The data from all of the ACSEP evaluations performed in FY 1999 are pooled together. The table column titled "Percent of All Facilities" presents the proportion of facilities evaluated that had systemic issues recorded. This presentation of the data is similar to that in *Subsection 3.5.1*, i.e., an analysis of the data with an industry perspective. The column titled "Percent of Applicable Facilities" provides the frequency systemic issues were reported at only those facilities where the criteria was implemented. This type of presentation of the data is similar to that made for the system elements in *Subsection 3.5.3*. As an example of this type of data, refer to the seventh row of *Table 3-6* (Criteria 5Q3). This row indicates that 15 systemic issues were recorded for this criteria in FY 1999 – three percent of all issues recorded in FY 1999. Additionally, three percent of all of the facilities evaluated were discovered to have issues with this criteria. However, this percentage includes facilities where this criteria did not apply. In only those facilities where the criteria applied, eight percent had systemic issues with it. In other words, whereas three percent of all facilities had systemic issues with performing special processes in accordance with process specifications, eight percent of the facilities that were actually performing special processes had systemic issues with following the process specifications.

3.7.1.1 Systemic findings and observations

The 11 evaluation criteria most frequently recorded with systemic issues are presented in *Table 3-6.* These 11 criteria accounted for almost 40 percent of all reported systemic issues. As a group, they occurred at 70 percent of the facilities with systemic issues.

TABLE 3-6.—Ten most reported criteria with systemic issues

Rank	Criteria	Description	Number of Systemic Issues	Percent of Systemic Issues	Percent of All Facilities	Percent of Applicable Facilities
1	4P9	Completed product/part identification	35	7%	8%	8%
2	10Q1	Initial & periodic evaluations of suppliers	27	5%	6%	8%
3	4Q1	Inspection methods and plans	21	4%	5%	5%
4	10Q10	Receiving inspection	19	4%	4%	5%
5	4P4	Work instructions control manufacturing processes	18	4%	4%	5%
6	15M1	Internal auditing program	17	3%	4%	6%
7	5Q3	Performing special processes in accordance with process specifications	15	3%	3%	8%
8	10Q8	Verification of raw material	14	3%	3%	4%
9	4Q5	Inspection records	13	3%	3%	3%
10	4M1	Operation within production limitations	12	2%	3%	3%
11	11Q1	Control of nonconforming products	11	2%	3%	3%

Table 3-7 illustrates that many of the most significant systemic issues have been significant for the last five years. The table lists the top ten most cited criteria for the last five years. The criteria are ranked by their significance over the five-year period. The columns: FY 1999, FY 1998, FY 1997, FY 1996, and FY 1995 indicate whether the criteria was a top issue for that year. Eight of the ten have been the top issues for four or more of the last five years.

TABLE 3-7.—Five-year trend of most predominant systemic issues – by criteria

5-Year Rank	Criteria		FY 1999	FY 1998	FY 1997	FY 1996	FY 1995
1	10Q1	Initial & periodic evaluations of suppliers	✘	✘	✘	✘	✘
2	4P9	Completed product/part identification	✘	✘	✘	✘	✘
3	15M1	Internal auditing program	✘	✘	✘	✘	✘
4	11Q1	Control of nonconforming products	✘	✘	✘	✘	✘
5	5Q3	Accord with process specifications	✘	✘	✘	✘	
5	4P4	Work instructions control manufacturing processes	✘	✘	✘		✘
6	10Q10	Receiving inspection	✘		✘	✘	✘
7	10Q5	Flow down of technical & quality requirements		✘	✘		✘
8	10Q8	Verification of raw material	✘			✘	
9	4Q5	Inspection records	✘	✘	✘		✘
		✘ Criteria within the top tenth percentile for the fiscal year					
		"blank" Criteria within the lower 90th percentile for the fiscal year					

3.7.2 A Facility Focus

This section lists the criteria issues separated by approval type (*Tables 3-8 to 3-10*). This allows the reader to focus on the issues pertinent to a particular approval type without bias from the other approval types. For example, the data from the relatively few PC holders is not skewed by the data from the much larger population of PMA holders.

As in the previous subsection (Table 3-6 the column titled "Percent of All Facilities") the table columns titled "Percent of (*approval holder*) with Issues" represent the proportion of facilities evaluated that had systemic issues recorded. The column titled "Percent of Applicable Facilities with Issues" provides the frequency that issues were reported at those facilities where the criteria were implemented. This column compares those criteria that are not widely utilized throughout industry on a level playing field with those criteria that are universally implemented.

For clarity, only the top issues are reported in this section (a full listing of the data can be found in *Appendix C*). Even though only 16 criteria are reported in these three tables, a third of all systemic issues are represented.

TABLE 3-8.—*Predominant systemic issues — PC holders*

Rank	Criteria	Description	Number of Systemic Issues	Percent of Systemic Issues for PC Holders	Percent of PC Holders with Issues	Percent of Applicable Facilities with Issues
1	4P4	Work instructions control manufacturing processes	5	6%	20%	20%
2	10Q10	Receiving inspection	4	5%	16%	16%
3	5Q2	Required qualifications/approvals	3	4%	12%	14%
3	15M1	Internal auditing program	3	4%	12%	14%
4	4Q5	Inspection records	3	4%	12%	12%
5	5Q3	Accord with process specifications	2	2%	8%	10%
6	10Q5	Flow down of technical & quality requirements	2	2%	8%	9%
7	8E1	Test procedures/instructions established	2	2%	8%	9%
7	8E2	Control of test procedure/instruction changes	2	2%	8%	9%
7	11Q2	Permanent identification of scrap material	2	2%	8%	9%

TABLE 3-9.—*Predominant systemic issues — PMA holders*

Rank	Criteria	Description	Number of Systemic Issues	Percent of Total Systemic Issues for PMA Holders	Percent of PMA Holders	Percent of Applicable Facilities with Issues
1	4P9	Completed product/part identification	30	10%	9%	9%
2	10Q1	Initial & periodic evaluations of suppliers	19	6%	5%	7%
3	4Q1	Inspection methods and plans	13	4%	4%	4%
4	10Q8	Verification of raw material	12	4%	3%	4%
5	5Q3	Accord with process specifications	9	3%	3%	6%
6	15M1	Internal auditing program	9	3%	3%	4%
7	4P4	Work instructions control manufacturing processes	9	3%	3%	3%
8	10Q10	Receiving inspection	9	3%	3%	3%

In addition to the eight criteria listed in *Table 3-9*, the following criteria warrants concern.

- Nondestructive inspection (NDI) operator qualifications (criteria 9Q1)

This criteria applies to only 11 percent of PMA holders. However, of those facilities where the criteria applies, eight percent of the facilities had systemic compliance issues with it. Should more PMA facilities use NDI, this criteria could become a major area of noncompliance.

TABLE 3-10.—*Predominant systemic issues — TSO authorization holders*

Rank	Criteria	Description	Number of Systemic Issues	Percent of Total Systemic Issues for TSO Authorizations	Percent of TSO Authorizations	Percent of Applicable Facilities with Issues
1	10Q1	Initial & periodic evaluations of suppliers	7	6%	14%	16%
2	10Q5	Flow down of technical & quality requirements	5	4%	10%	11%
3	4Q1	Inspection methods and plans	5	4%	10%	10%
3	10Q10	Receiving inspection	5	4%	10%	10%
4	5Q3	Accord with process specifications	4	3%	8%	18%
5	15M1	Internal auditing program	4	3%	8%	11%
6	4M1	Operation within production limitations	4	3%	8%	8%
7	1Q4	Quality manual	4	3%	8%	8%

In addition to the eight criteria listed in *Table 3-10*, the following two criteria warrant concern.

- Software Configuration Management Plan (criteria 3AE1)
- Programmed media handling/storage (criteria 3AQ1)

These criteria apply to only 16 percent of TSO authorizations. However, of those facilities where the criteria do apply, 25 percent of those facilities had systemic compliance issues with them. Should these two criteria become applicable to more TSO authorizations, these criteria could become major areas of noncompliance. It should also be noted that, in those facilities that produce software, these two criteria are the most pervasive compliance issues.

3.8 Trend Analysis

ACSEP evaluation results have been collected in a standard and consistent manner sufficient to allow trend analysis since FY 1995. The trend analyses are presented in a series of figures and tables throughout this section. The figures present several pieces of information. The data points represent the proportion of facilities that had systemic issues reported for each of the given fiscal years. Error bars (the vertical lines through each point) are provided for each data point. The error bars report the amount of statistical error associated with extrapolating the actual data collected to the entire population — including those facilities not evaluated. Each figure also contains two sets of trend lines. The solid line is the linear regression trend for the data points. The dotted lines are the positive and negative statistical error for the trend line. A 90 percent confidence level was used in all cases to determine if a significant trend was indicated (an explanation as to the selection of the confidence level is discussed further in *Appendix E*).

Please note that the facility data presented in the following figures is not adjusted for the differences in system complexity among the various approval types. Therefore, the data for each approval type should be considered separately; and no comparison between approval types should be made with these charts (refer to *Section 3.5* for comparisons between approval types).

3.8.1 Systemic Issues

Overall, the percentage of facilities with systemic issues reported has dropped about three percent per year. The proportion of PC holders and TSO authorizations with systemic issues reported appears to be flat. Nine percent fewer PMA holders had issues reported than five years ago. The results of these trend analyses are presented in *figures 3-15 through 3-18*.

The data for PC holders appears to have an annual cyclical fluctuation (*see figure 3-16*). This fluctuation appears to be caused by a sampling bias introduced at the inception of ACSEP. Due to the relatively small number of PC holders, and the relative critical nature of these facilities, it is theorized that the initial selection of facilities to evaluate was not random. The other approval types would be far less affected by the initial selection bias. The greater number of facilities in the other approval types lessens the impact that a targeted selection of a few facilities would have on an otherwise random selection of facilities. For this reason, PC holder information in this report is presented with two consecutive years pooled.

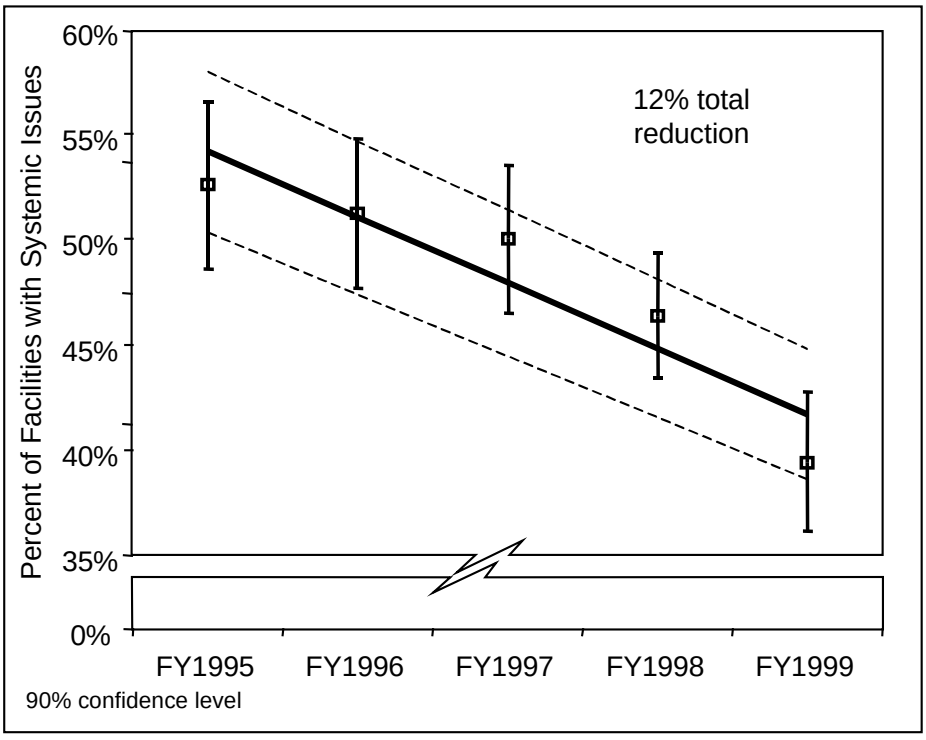

Figure 3-15.— Trend data for systemic issues — overall.

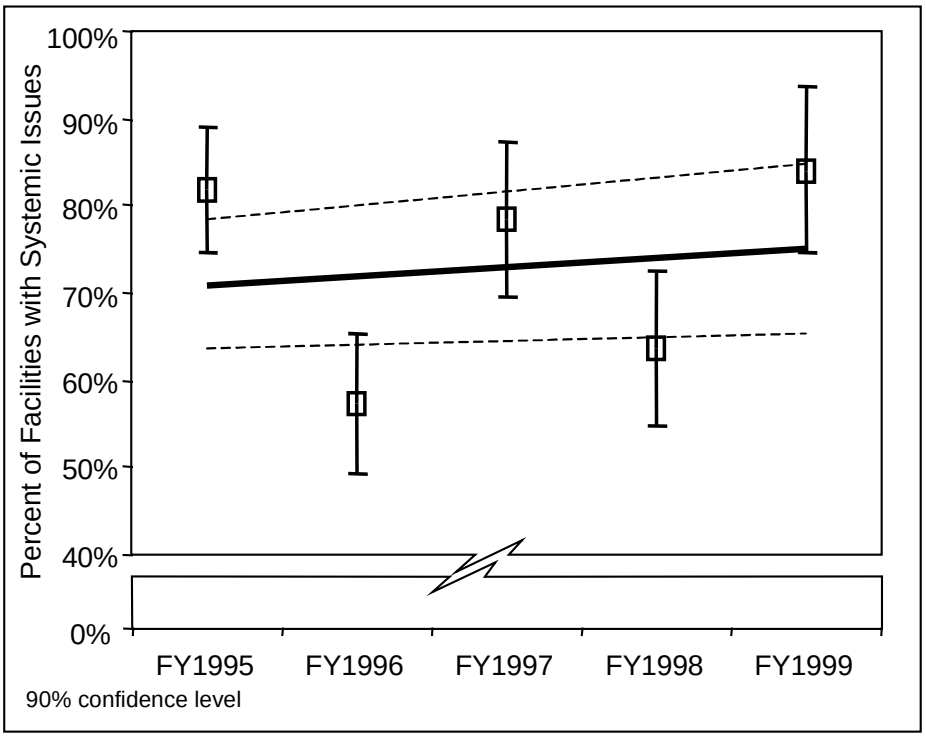

Figure 3-16.— Trend data for systemic issues — PC holders.

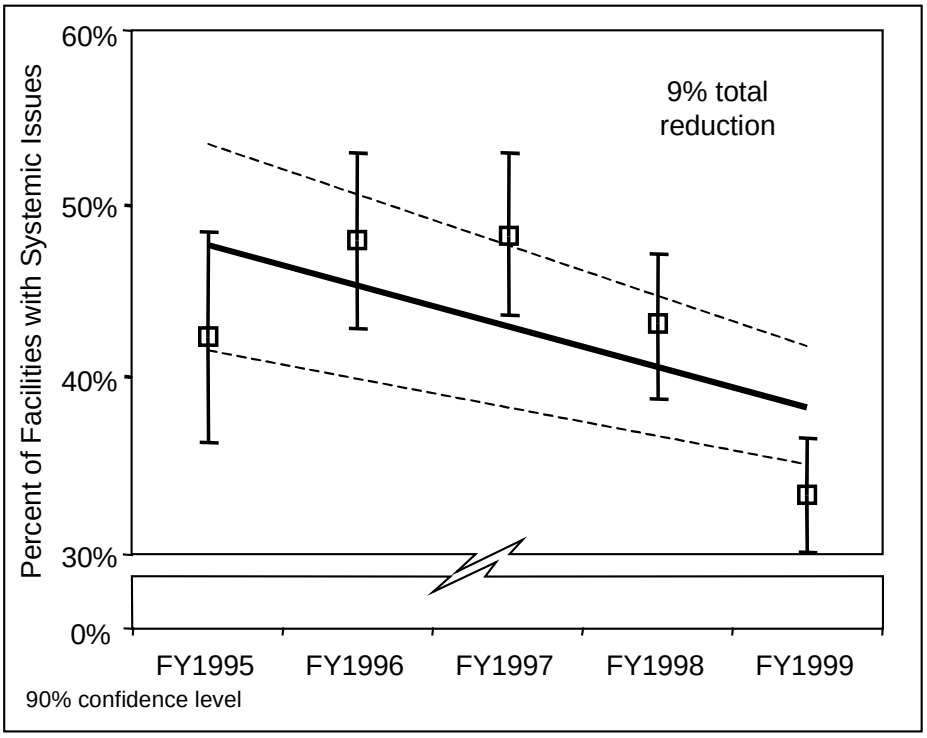

Figure 3-17.— Trend data for systemic issues — PMA holders.

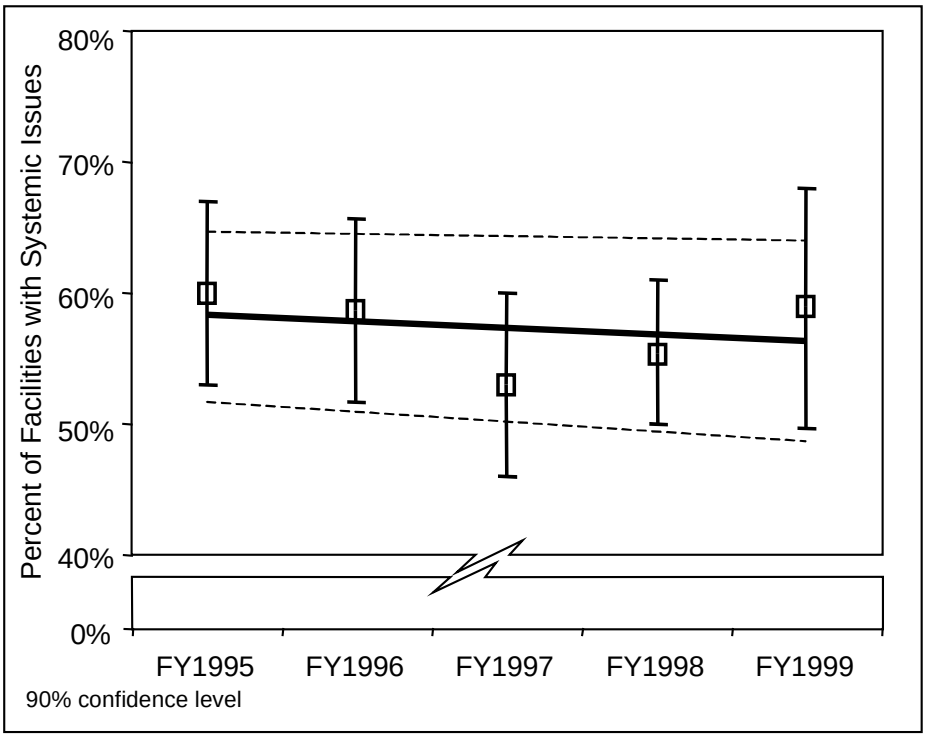

Figure 3-18.— Trend data for systemic issues — TSO authorizations.

3.8.1.1 Systemic issue trends at the system element level

The percentage of facilities with systemic issues appears to have dropped within most of the system elements. Of the most predominant system elements, only two did not have a significant reduction in facilities with reported systemic issues. The five-year trends are listed in *Table 3-11* and displayed in detail in *figures 3-19 through 3-25*.

TABLE 3-11.—*Trends of the most predominant system elements*

System element name	Five-year Trend
Manufacturing Processes	7% drop
Supplier Control	8% drop
Design Data Control	7% drop
Tool and Gauge	Slight drop but not yet significant
Nonconforming Material	5% drop
Special Manufacturing Processes	Flat
Material Handling and Storage	6% drop

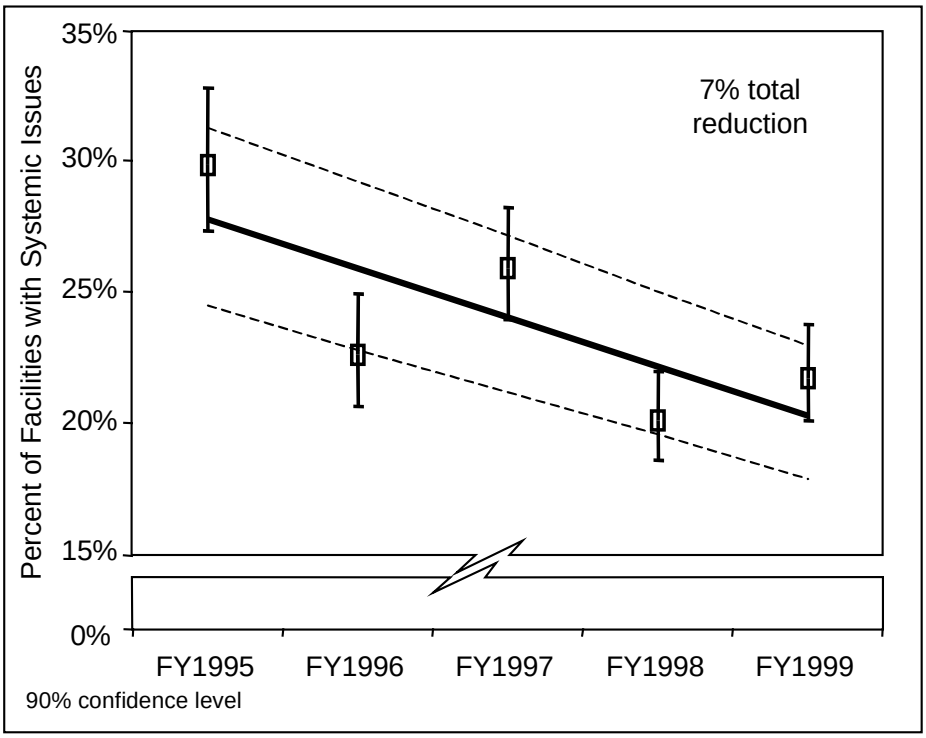

Figure 3-19.—Trend data for systemic issues — manufacturing processes.

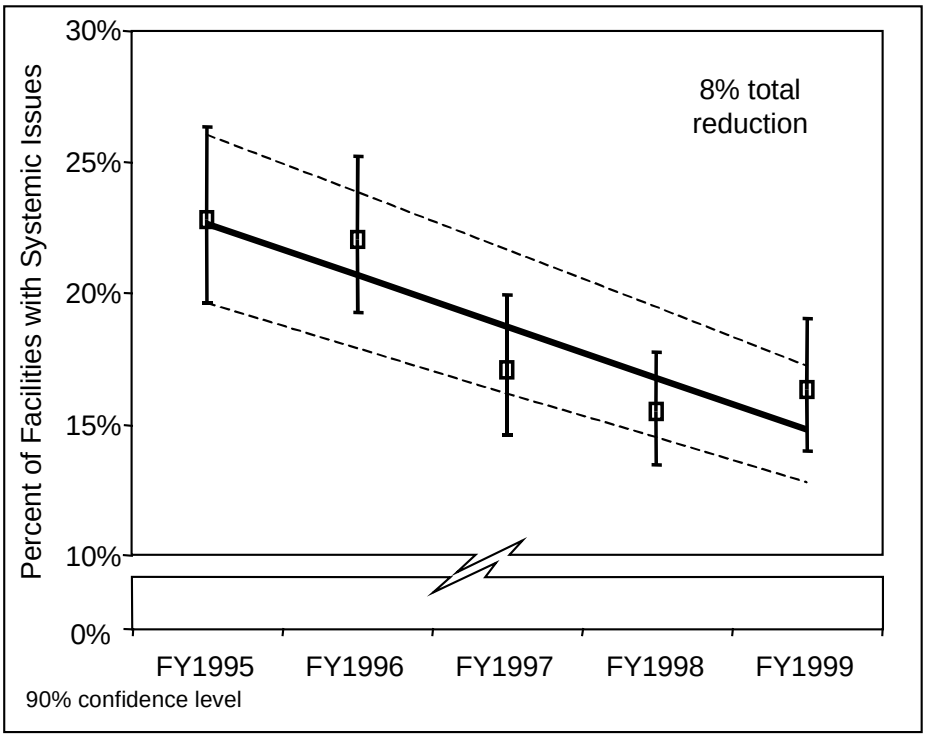

Figure 3-20.— Trend data for systemic issues —supplier control.

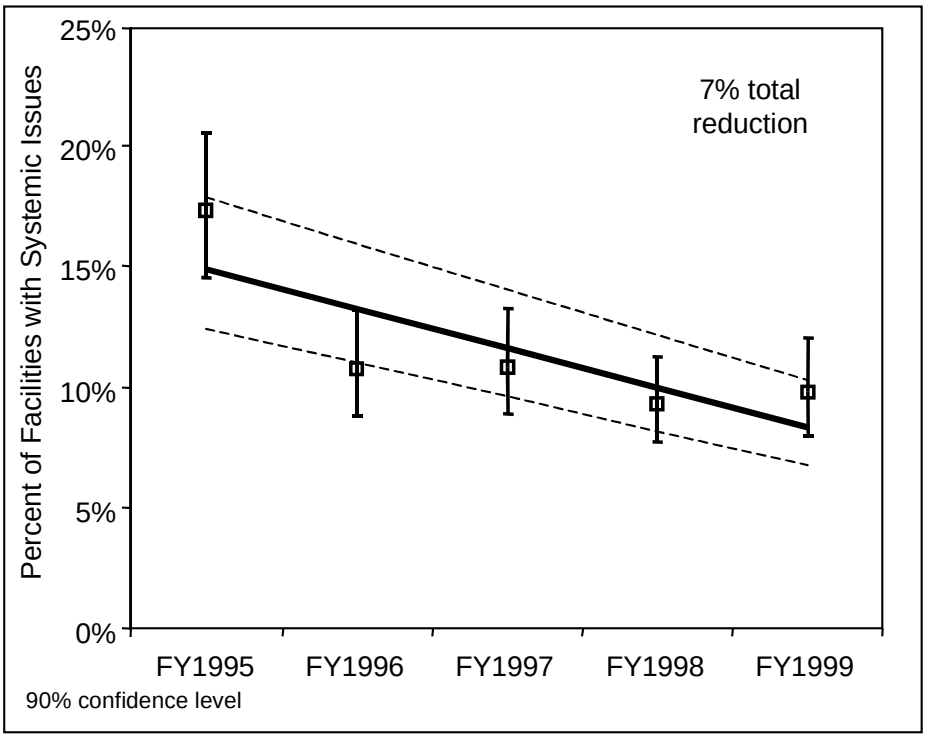

Figure 3-21.— Trend data for systemic issues — design data control.

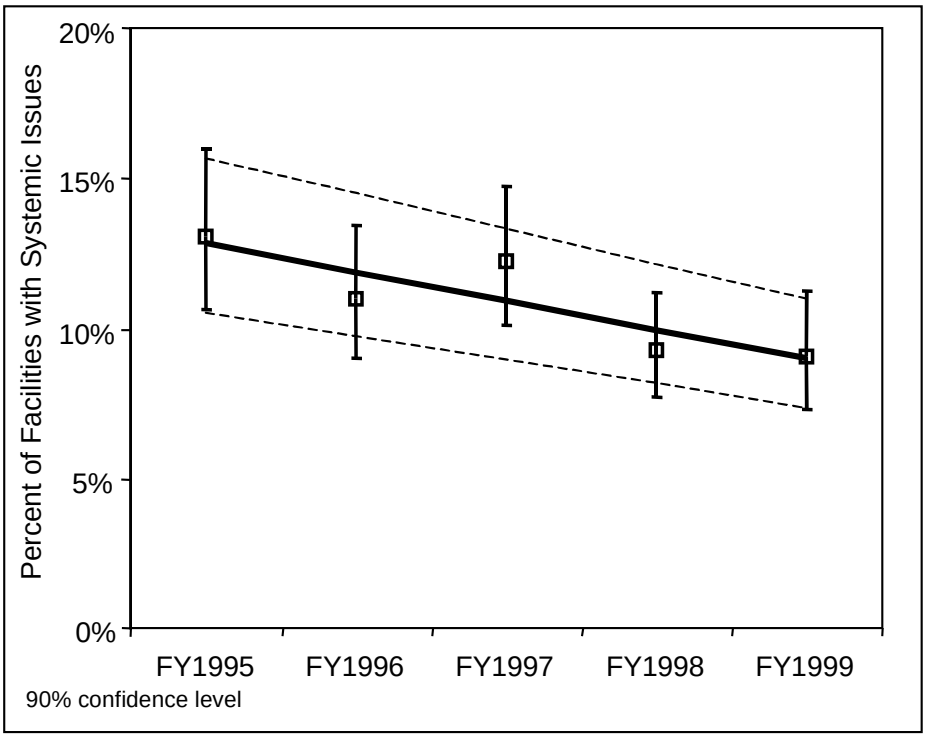

Figure 3-22.— Trend data for systemic issues — tool and gauge.

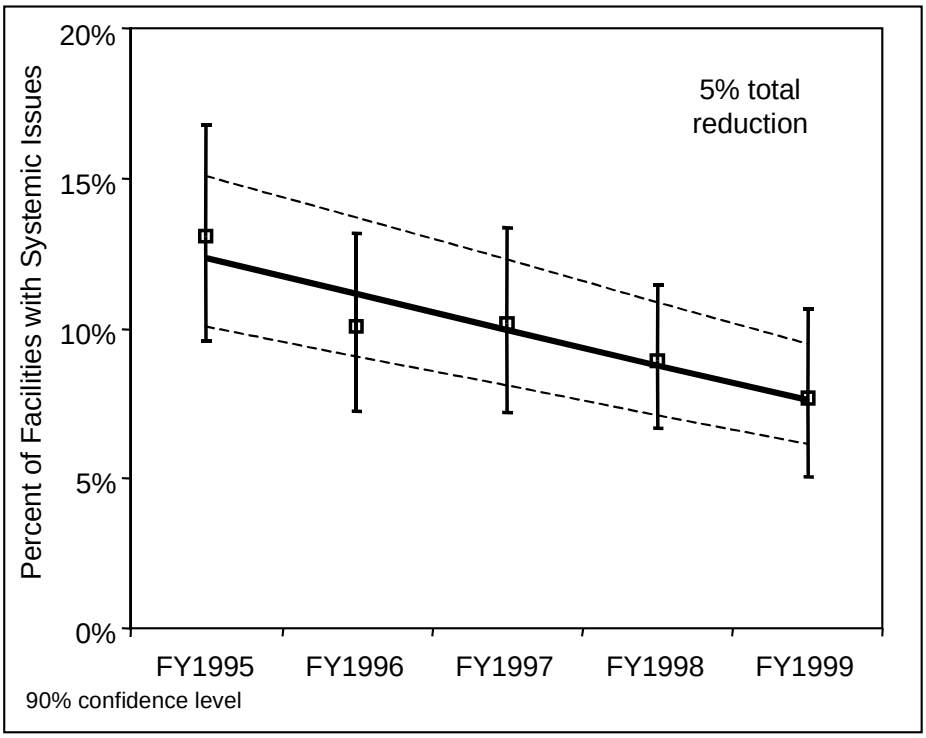

Figure 3-23.— Trend data for systemic issues — nonconforming material.

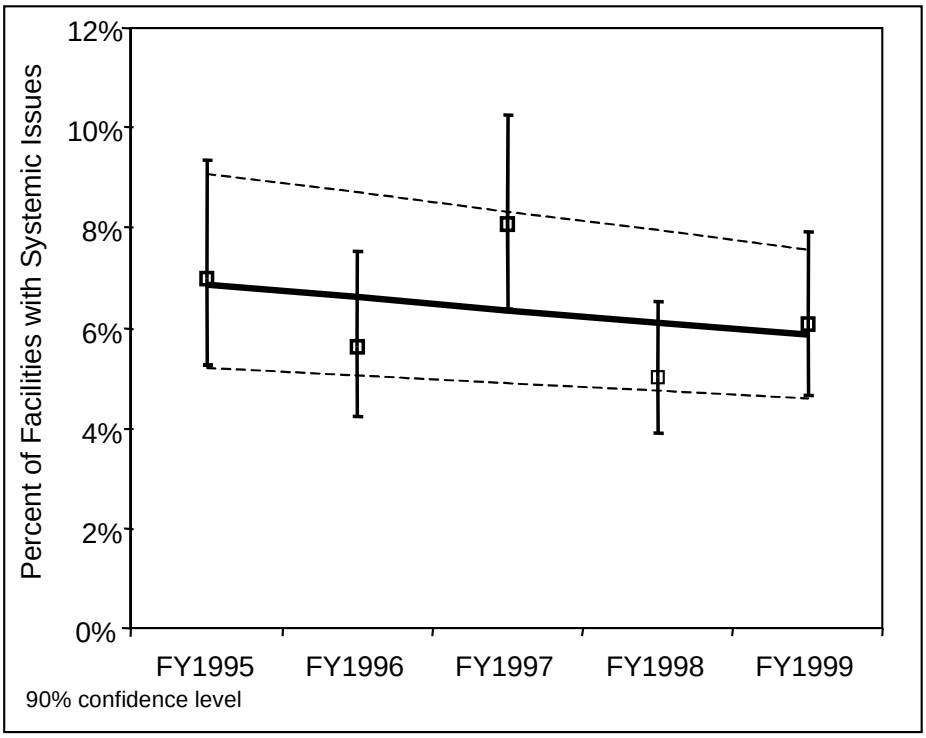

Figure 3-24.— Trend data for systemic issues — special manufacturing processes.

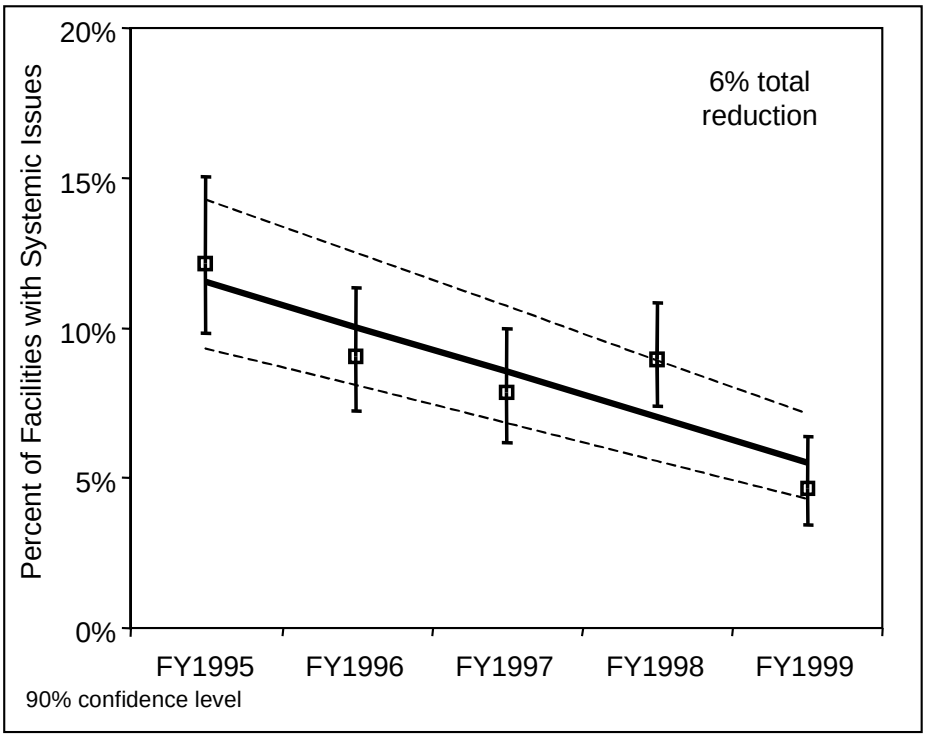

Figure 3-25.— Trend data for systemic issues — material handling and storage.

As reported in *Section 3.6*, material handling and storage was replaced by special manufacturing processes as the sixth most cited system element for systemic issues. As shown in *figures 3-24 and 3-25*, this is because there was a drop in material handling issues reported while special manufacturing processes issues remained flat. If these trends continue, we should see more of the most predominant system elements being replaced by lesser reported system elements.

3.8.1.2 Systemic issue trends at the criteria level

Half of the criteria that had the most reported systemic issues over the past five years have demonstrated a statistically significant downward trend. Another third demonstrate, while not statistically significant, slight to moderate downward trends. The remaining three criteria have remained flat over the last five years. Some of these criteria currently have systemic issues reported at less than one percent of the facilities evaluated. None of the most prominent criteria show an upward trend. *Table 3-12* provides a summery of these trends.

TABLE 3-12.—*Five-year trend of systemic issues—criteria level*

5-Year Rank	Criteria		Trend
1	10Q1	Initial & periodic evaluations of suppliers	8% downward
2	4P9	Completed product/part identification	Flat
3	15M1	Internal auditing program	6% downward
4	11Q1	Control of nonconforming products	5% downward
5	4P4	Work instructions control manufacturing processes	Slightly downward
5	5Q3	Special processes accomplished in accordance with process specifications	Moderately downward
6	10Q10	Receiving inspection	Slightly downward
7	10Q5	Flow down of technical & quality requirements	3% downward
8	10Q8	Verification of raw material	Slightly downward
9	4Q5	Inspection records	Slightly downward
10	10Q2	Use of approved suppliers	4% downward
11	12Q5	Identification of age control products	3% downward
12	4Q1	Inspection methods and plans	Flat
13	7Q1	Approval/inspection of tools & gauges	3% downward
14	4M1	Operating within production limitations	Flat
15	12Q3	Storage of conforming parts	Slightly downward
16	11Q2	Permanent identification of scrap material	Slightly downward
17	2E2	Drawing control system	4% downward
18	2E1	Design change approval	3% downward (currently at 1%)
19	4Q3	Issuance of inspection stamps	Flat
20	10Q12	Records of receiving inspection	3% downward (currently less than 1%)

3.8.2 Isolated Observations

Isolated observations also appear to be trending downward overall (*figure 3-26*). PMA holders have had the most dramatic reduction of the approval types (*figure 3-28*) and contributed mostly to the overall trend. This is largely due to a clarification of the quality manuals of PMA holders. The quality system manuals of PMA holders are not FAA-approved documents. Prior to FY 1997 it was largely held that these manuals were FAA-approved. Isolated observations are only recorded for those issues that are either

related directly to a noncompliance with CFR requirements or noncompliance with FAA-approved documentation. Once PMA quality manuals were universally regarded as not FAA-approved, there was a dramatic reduction in the number of isolated observations from PMA holders.

The five-year trend for PC holders is flat and mirrors the trend for systemic issues (*figure 3-27*). TSO authorizations have slightly fewer facilities with isolated issues reported (*figure 3-29*).

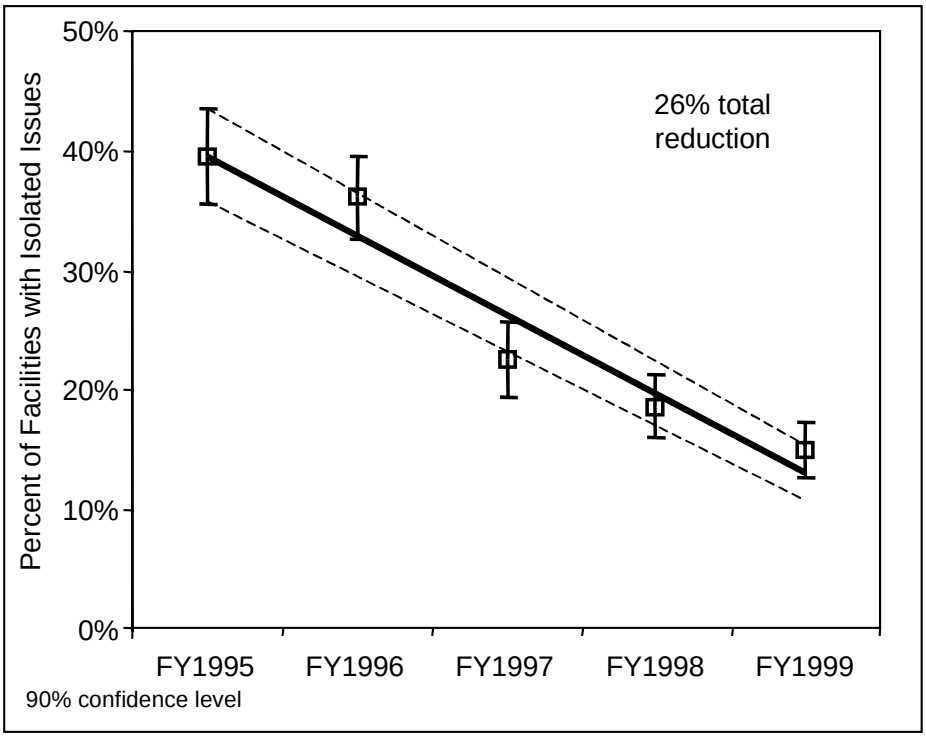

Figure 3-26.—Trend data for isolated observations —overall.

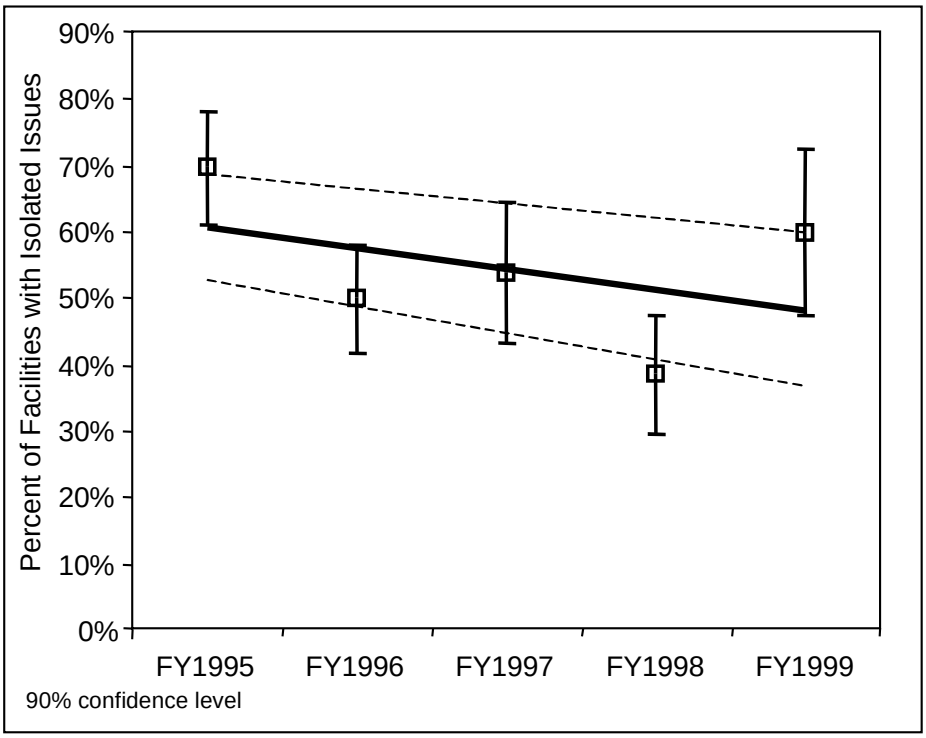

Figure 3-27.— Trend data for isolated observations —PC holders.

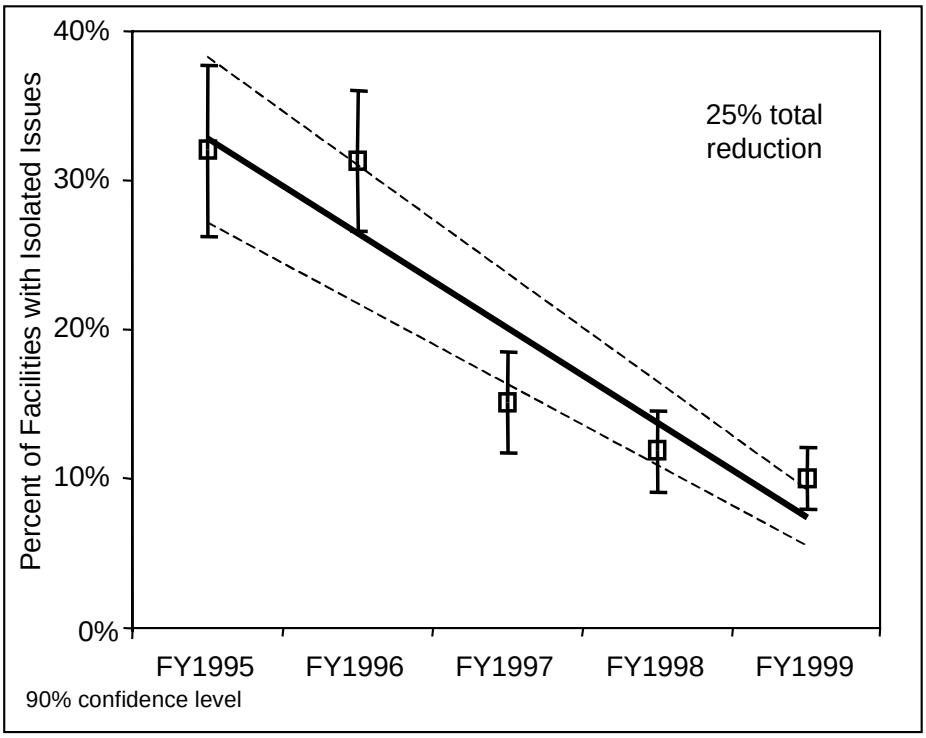

Figure 3-28.— Trend data for isolated observations —PMA holders.

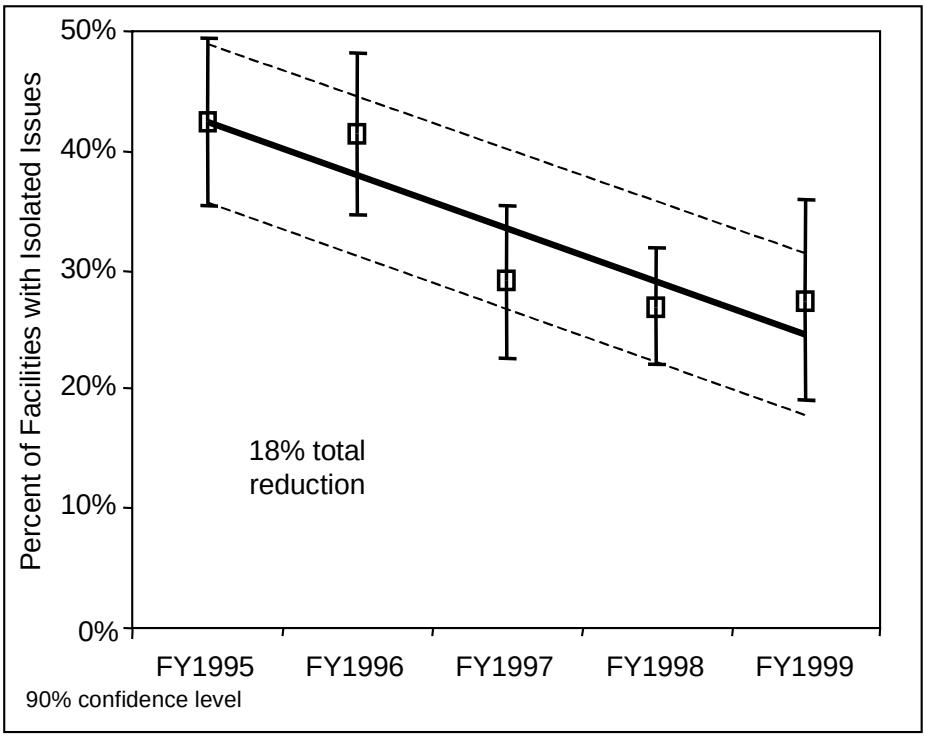

Figure 3-29.— Trend data for isolated observations —TSO authorizations.

3.8.3 CFR-based Observations

CFR-based observations also are trending downward. There were only 19 CFR-based observations reported for FY 1999. Over the last five years, facilities with reported CFR-based observations have dropped nine percent (*figure 3-30*). The trend for PC holders is flat; however, there were only four CFR-observations reported for FY 1999 (*figure 3-31*). This flat trend is due largely to the fact that there were so few CFR-based observations reported for PC holders over the last five years. PMA holders with CFR-observations reported have dropped eight percent (*figure 3-32*). This trend is significant because there have been a moderate number CFR-based observations reported in years past. TSO authorizations are trending slightly downward; however, there were only four CFR-based observations reported for TSO authorizations for FY 1999 (*figure 3-33*).

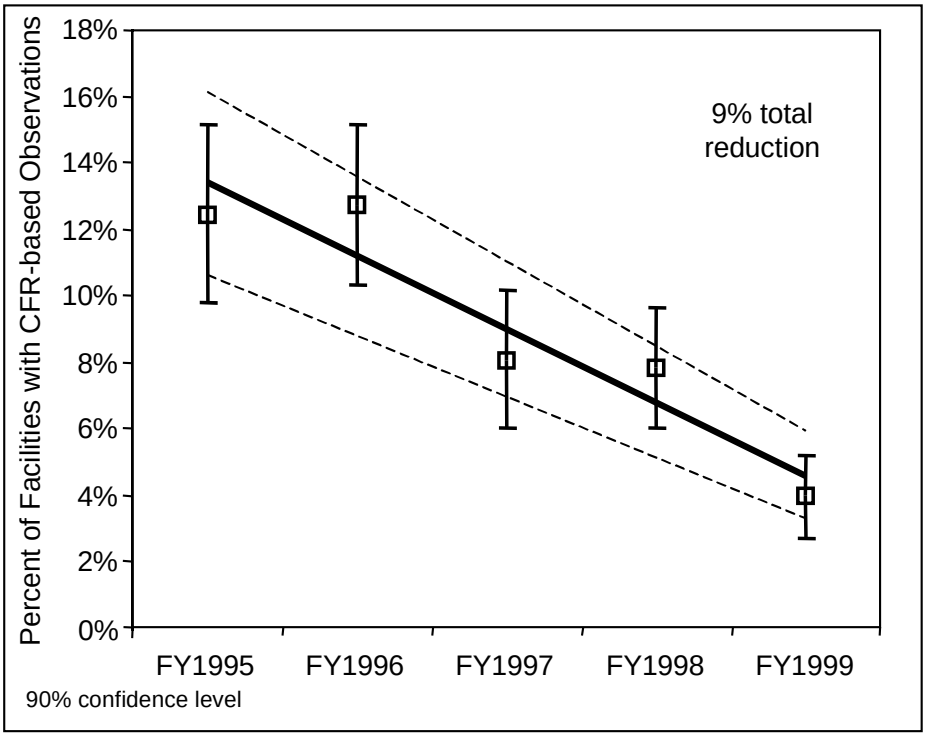

Figure 3-30.— Trend data for CFR-based observations —overall.

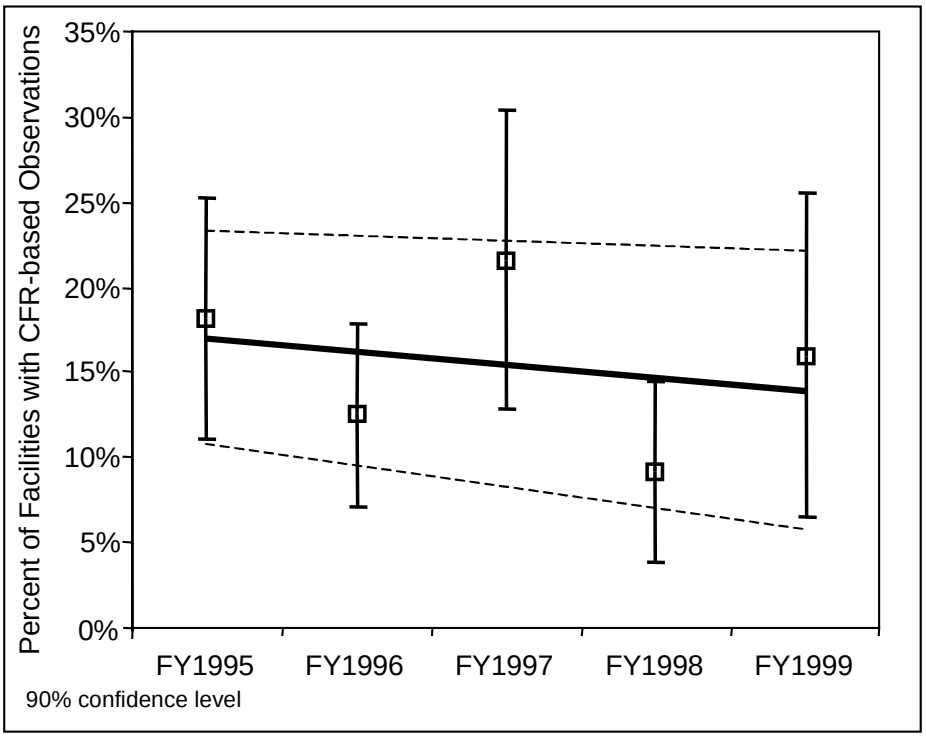

Figure 3-31.— Trend data for CFR-based observations —PC holders.

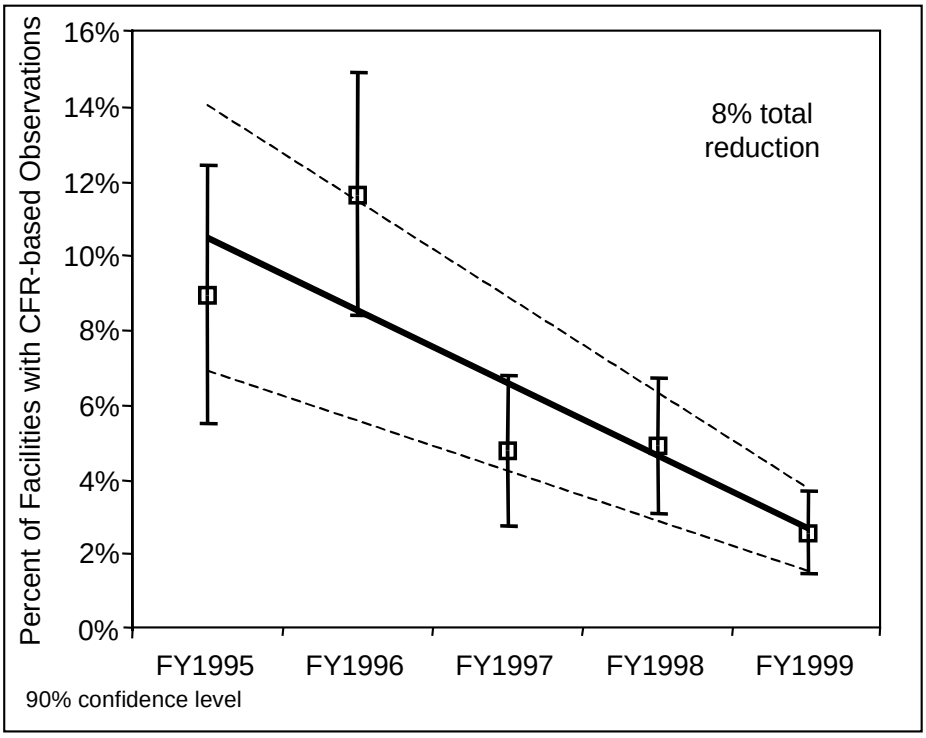

Figure 3-32.— Trend data for CFR-based observations —PMA holders.

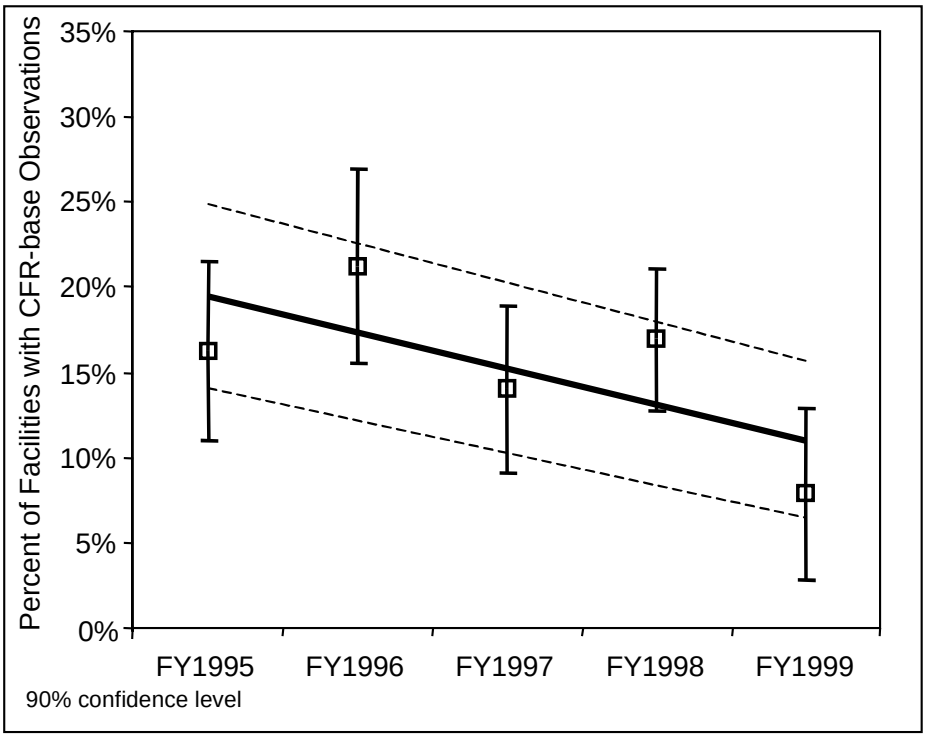

Figure 3-33.— Trend data for CFR-based observations —TSO authorization holders.

3.9 Internal Audit

3.9.1 What is the Impact of a Discrepant Internal Audit Program?

Building on an analysis introduced in the FY 1996 report, an analysis was performed on the differences between facilities with and without an effective internal audit program. The first part of the analysis focused only on those facilities that used internal audit systems. The analysis sought to determine a facility would have issues in areas other than the internal audit area if they did not follow their established internal audit procedures. The following definitions were used:

Effective audit program - The facility had implemented an internal audit program as described in Order 8100.7 and had not received findings nor systemic observations in the Internal Audit system element. It should be noted that no qualitative assessment of the internal audit program was made by the FAA. Any facility with an internal audit program, as defined in Order 8100.7, that was found to be in compliance with its own procedures and policies was deemed to have an effective internal audit program for the purposes of analysis only.

Ineffective internal audit program - Those facilities where an internal audit program was in place, but that program had findings or systemic observations against it. *Please note, the findings and observations against the internal audit program were subtracted in order to provide an unbiased analysis.*

No internal audit program - Facilities where internal audit was determined to be either not in place or not applicable. *Facilities where the Internal Audit system element had not been evaluated were not included in the analysis as their internal audit status could not be ascertained. Any facility that received a finding or systemic observation for their internal audit program because the documented internal audit program had not yet been implemented or had not been used for several years was also excluded from the analysis.*

Several analysis methods were used in order to verify the results: chi-squared contingency tables, confidence intervals, pooled Z-tests for significance, and logistic analysis controlling for system complexity (as seen in the *figure 3-34*). All tests were very conclusive; i.e., ***facilities with systemic issues reported in their internal audit program were 16 times more likely to have additional systemic issues than facilities that followed their established internal audit procedures***. In fact, almost all of the

facilities having systemic issues with their internal audit programs also had systemic issues in other areas.

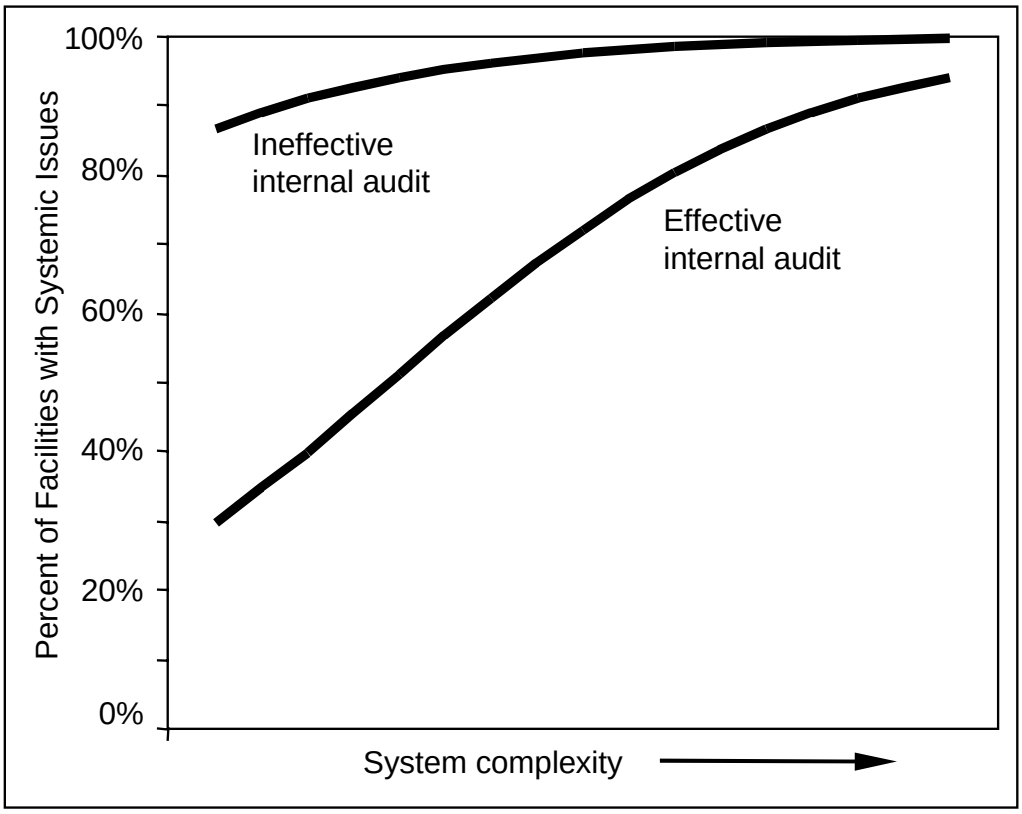

Figure 3-34.—Comparison of systemic issues for facilities with effective and ineffective internal audit programs.

In addition to an increased probability of issues, facilities with ineffective internal audit programs also had more issues than those with effective internal audit programs. *Figure 3-35* focuses on only those facilities that had systemic issues. Even when the internal audit issues were subtracted for those facilities with ineffective internal audit, they still had twice the number of reported issues. In fact, those facilities with ineffective internal audit had even more findings than those facilities that had never instituted internal audit.

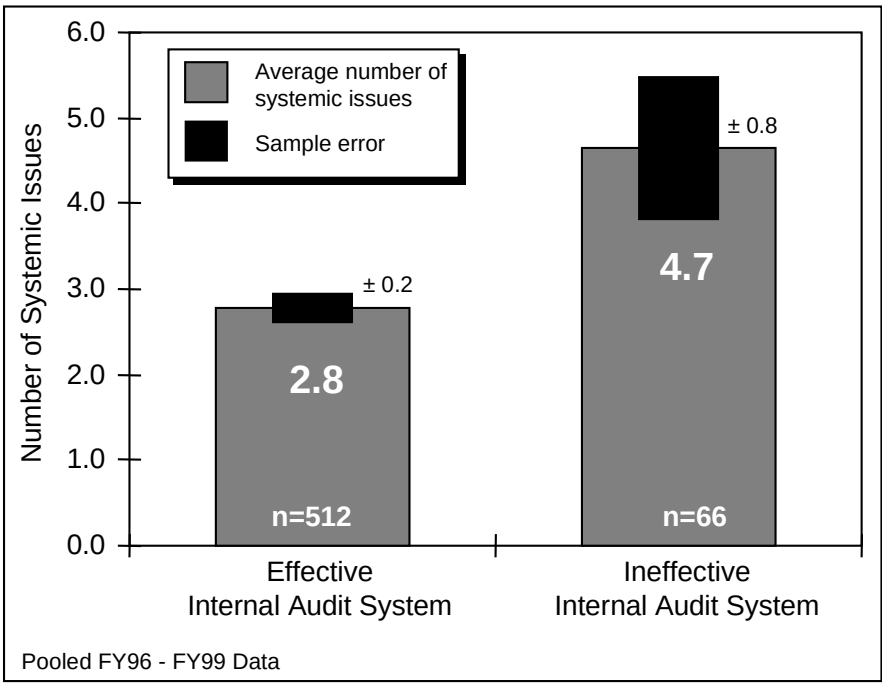

Figure 3-35.—Comparison of systemic issues for facilities with effective and ineffective internal audit programs.

3.9.2 Does an Internal Audit Program Reduce Findings and Observations?

The next part of the analysis looks at the relationship between facilities with and without internal audit programs. Whether there was a relationship between internal audit and the probability of reported systemic issues was dependent upon the complexity of the facilities systems (*figures 3-36 and 3-37*). For facilities with simple systems, there was virtually no difference between facilities with internal audit and those facilities without internal audit. As the quality and production systems of a facility became more complex, however, facilities with internal audit programs were less likely to have systemic issues reported. Large facilities with complex systems seem to benefit from an internal audit program, whereas, internal audit does not seem to matter for small facilities with simple systems. This same type of relationship is present for the number of issues reported.

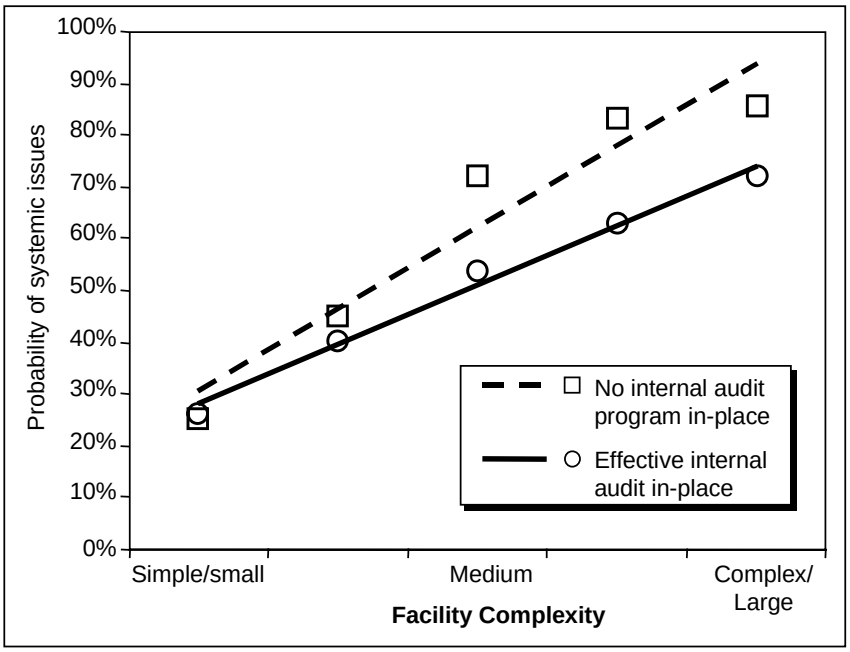

Figure 3-36.—The affect of an internal audit program on compliance.

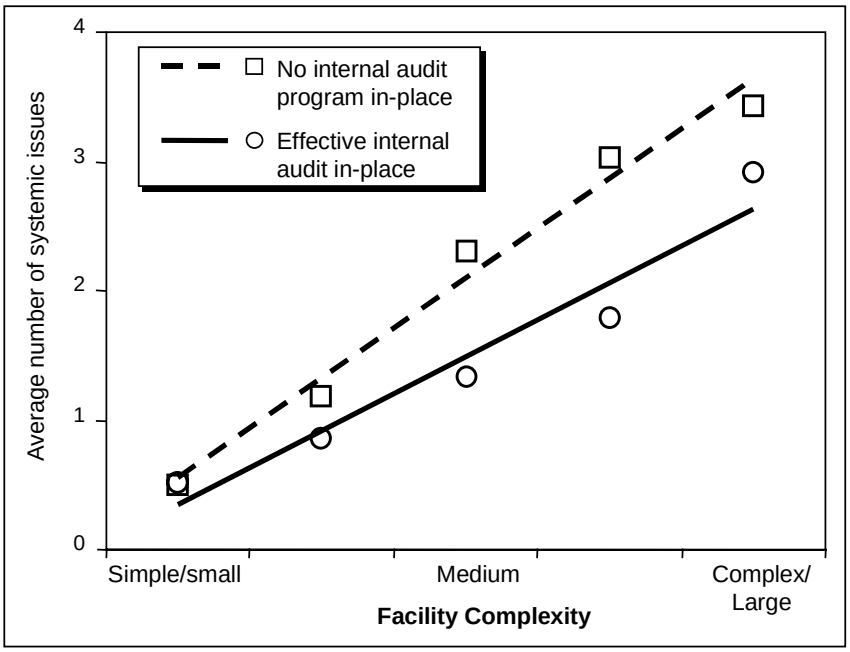

Figure 3-37.— The affect of an internal audit program on the number of findings and systemic observations.

Several factors could account for the relationship between facility complexity and internal audit. First, an internal audit program could be an effective means of ensuring that

process changes are documented. In essence, internal audit could provide a systematic approach to process and procedural review. Therefore, for large facilities with many procedures, internal audit would help assure that a continuous review of procedures occurred. Another factor (assuming that internal audit is causing the difference in compliance) may be that larger facilities with complex quality systems have more comprehensive internal audit programs in place. Current ACSEP evaluations do not assess the level nor the depth of implementation of internal audit programs. No distinction is made, for example, between a facility utilizing only statistical sampling on a small portion of their processes and that of a facility with a fully deployed, root-cause corrective action internal audit program with regular status reviews by upper management.

Notwithstanding the above, this year's analysis has yielded a significantly better understanding of the relationship between internal audit and general procedural compliance.

3.10 Supplier Control

One out of every seven production approval holders had a systemic supplier control issue reported during an ACSEP evaluation — the second most frequently reported issue. As producers of aircraft parts offload more and more of their production process to suppliers, issues with the control of those suppliers have an increasing importance. Our goal is to discover any trends that can guide us to reduce the unacceptably high noncompliance with supplier control procedures and requirements.

3.10.1 The Issues are at the Production Approval Holders, Not the Suppliers!

The first characteristic to be revealed about the issues reported was that ***the issues were not supplier issues, but, rather the failure of production approval holders to comply with the procedures and regulatory requirements for controlling their suppliers***. Supplier facilities had considerably fewer issues reported[10] than production approval holder facilities (*figure 3-38*). The chances of a supplier facility having systemic issues are only 40 percent those of a production approval holder having systemic issues. In addition, the number of supplier facilities with systemic issues was falling by a rate of eight percent per year — a far steeper decline than any of the production approval types (see *figure 3-39*).

[10] Insufficient data collected in FY 1999, this analysis based on FY 1998 data. All indications indicate that the FY 1995 through FY 1998 downward trend would have continued. Therefore, the difference between production approval holders and suppliers would have been the same or greater for FY 1999.

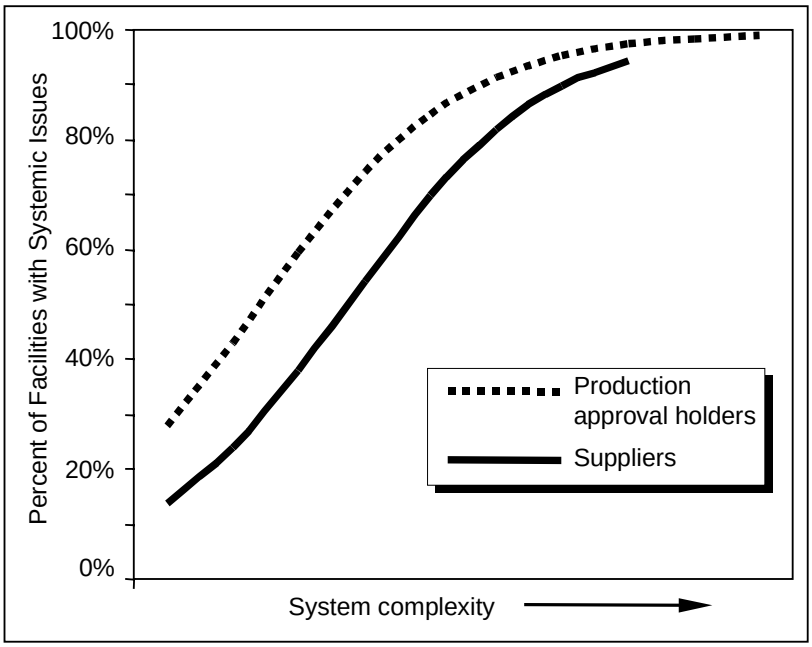

Figure 3-38.—Comparison of suppliers and PAH holders.

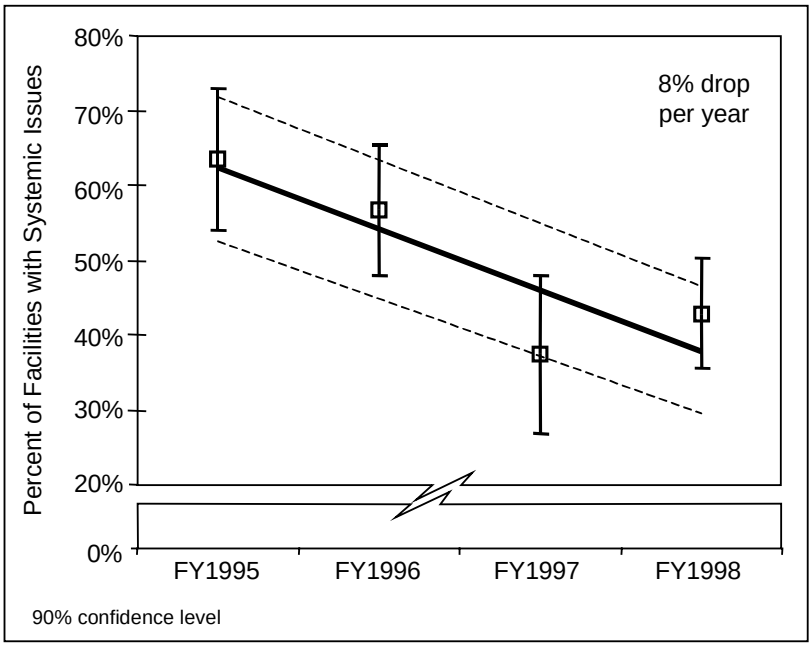

Figure 3-39.—Trend data for systemic issues — suppliers.

3.10.2 What are the Supplier Control Issues?

The detailed analysis centered on the encountered conditions reported during FY 1998 and FY 1999 for each supplier control finding and observation. To document a finding or an observation, the ACSEP evaluator will describe the encountered condition by giving a detailed explanation of:

- Why the encountered condition differs from the required condition.
- Where the encountered condition was found.
- The number of items checked and the number to be discrepant.
- The items found to be in noncompliance.
- All evidence that supports the finding or observation.

Some very striking patterns emerged from this analysis. Almost 40 percent of the issues were of a very serious nature, e.g., parts being procured from unqualified suppliers, receiving inspection not being performed, use of unapproved calibration facilities, etc. ***The analysis also revealed that 90 percent of the supplier control issues fell into seven major areas***:

Major issue area	Proportion of total supplier control issues
Use of unqualified suppliers	21%
Performing supplier control tasks to unapproved or outdated procedures	15%
Failure to re-survey suppliers on schedule in order to determine their capability to meet requirements	14%
Issues of an administrative nature, e.g., not using the proper form, not signing a document, etc.	13%
A general failure to flow down applicable technical and quality requirements to suppliers	11%
Failure to control the suppliers' design data	9%
Inability to trace the physical properties of raw material	8%

3.10.3 The Various Approval Types Have Different Issues

The use of unqualified suppliers is overall the most common issue. However, the proportion of facilities that were noncompliant with the requirement to use qualified suppliers is not the same for the various approval types. As an example, TSO authorizations are twice as likely to use unqualified suppliers as PMA holders and four times as likely as PC holders. *Table 3-13* lists the most common issues for each of the

approval types. The table clearly demonstrates that the issues are different at the various approval holders. There is no universal cure. Each approval type is unique and should adapt its own improvement strategy accordingly. *Table 3-13* can be used as a guide to direct the initial improvement effort. Facilities should then tailor their approach based upon their findings.

TABLE 3-13.—The most common supplier control issue

	Percentage of facilities with issues that had these particular issues
PC holders	
A general failure to flow down applicable technical and quality requirements to suppliers	25%
Performing tasks to unapproved or outdated procedures	23%
Failure to control the suppliers' design data	21%
PMA holders	
Use of unqualified suppliers	29%
Failure to re-survey suppliers on schedule in order to determine their capability to meet requirements	17%
Inability to trace the physical properties of raw material	13%
TSO authorizations	
Use of unqualified suppliers	30%
Failure to re-survey suppliers on schedule in order to determine their capability to meet requirements	16%
Performing tasks to unapproved or outdated procedures	12%

4. Improvement Emphasis

The goal of the ACSEP is to support continuing operational safety and promote continuous improvement.

4.1 Industry Feedback

As part of the ACSEP Quality Improvement Program, a performance feedback report (FAA Form 8100-7, FAA ACSEP Evaluation Feedback Report) is provided to each individual organization when notified that an evaluation is scheduled to take place. Each facility evaluated is requested to use this report to critique the FAA ACSEP evaluation process. The feedback report is used to record the facility's impression for each step of the evaluation, from notification to the post-evaluation conference. A question concerning the professionalism of the ACSEP evaluation team is also included on the report. The facility's management is encouraged to complete the report and return it for analysis. Feedback reports were returned by 46% of the facilities, which is the same as the previous year.

Overall, the feedback was very good. As with the previous year, greater than 99 percent of the responses were "Satisfactory" or better (see *figure 4-1*). The Directorate Continuous Improvement Team (DCIT) will make the evaluators aware of industry feedback that accounted for the very small percentage of "Poor" and "Unsatisfactory" responses. *Figure 4-2* gives the average scores for each of the feedback categories measured and an overall average. The data presented remains consistent from the previous years.

The feedback report also allows for the inclusion of comments/suggestions. The comments/suggestions dealt primarily with the issues of scheduling, providing materials to the facility prior to the ACSEP team's arrival, and ISO-9000. Examples of comments/suggestions submitted include:

- Would like more advanced notice of the audit.
- Too much time scheduled for the audit.
- Too many inspectors for the size of the facility.
- Provide the in-brief slides prior to the team's arrival.
- Provide a preliminary copy of FAA Form 8100-4, ACSEP Survey Sheet for Production Approval Holders to the facility evaluated.
- Provide a proposed schedule of when each system element will be evaluated.
- Provide a detailed explanation as to why ISO-9000 (International Organization for Standardization 9000 series of quality management standards) certification is not good enough to exempt a facility from the ACSEP process.

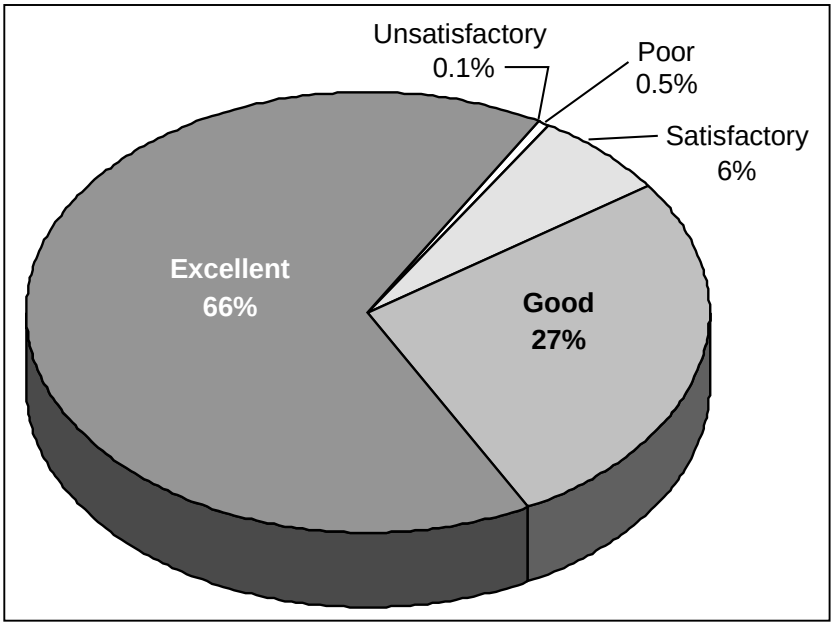

Figure 4-1.—Distribution of industry feedback.

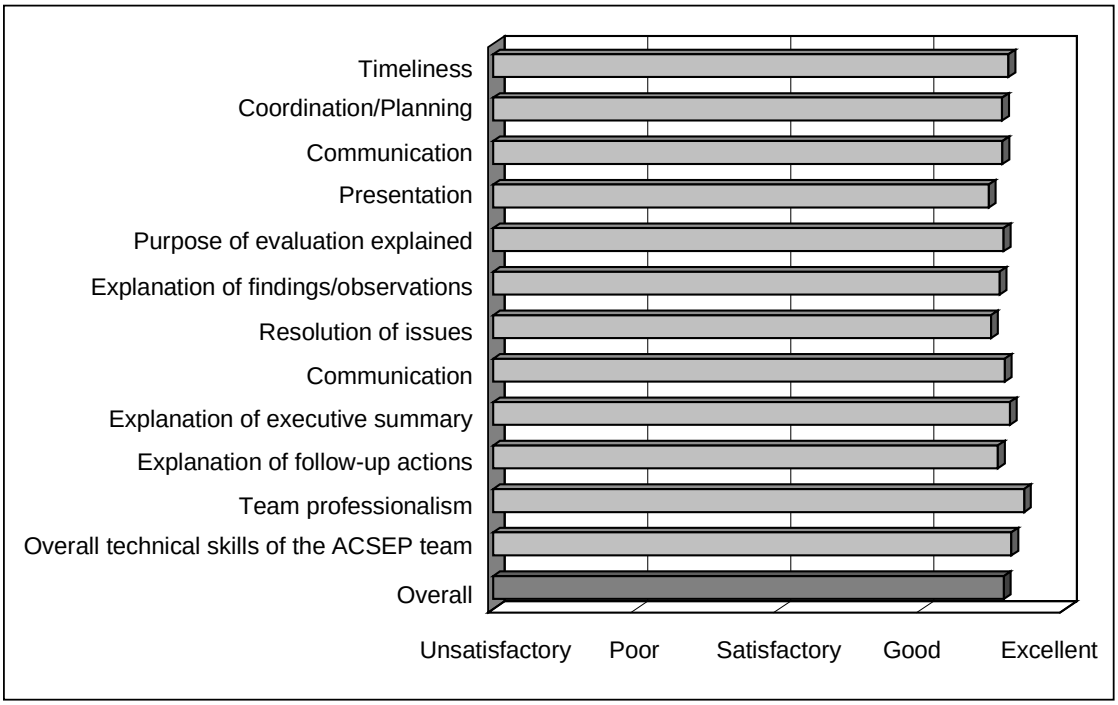

Figure 4-2.—ACSEP as graded by industry.

4.2 Lessons Learned

An additional part of the continuous improvement process is the gathering and analyzing of lessons learned that the evaluation team documented at the conclusion of each ACSEP evaluation. Each ACSEP evaluation team submits a "lessons learned" form that records the team's general assessment of the evaluation, difficulties with the order, system elements not evaluated, and any proposed new criteria. *Figure 4-3 through figure 4-6* show the trend in these lessons learned from FY 1994 to FY 1999.

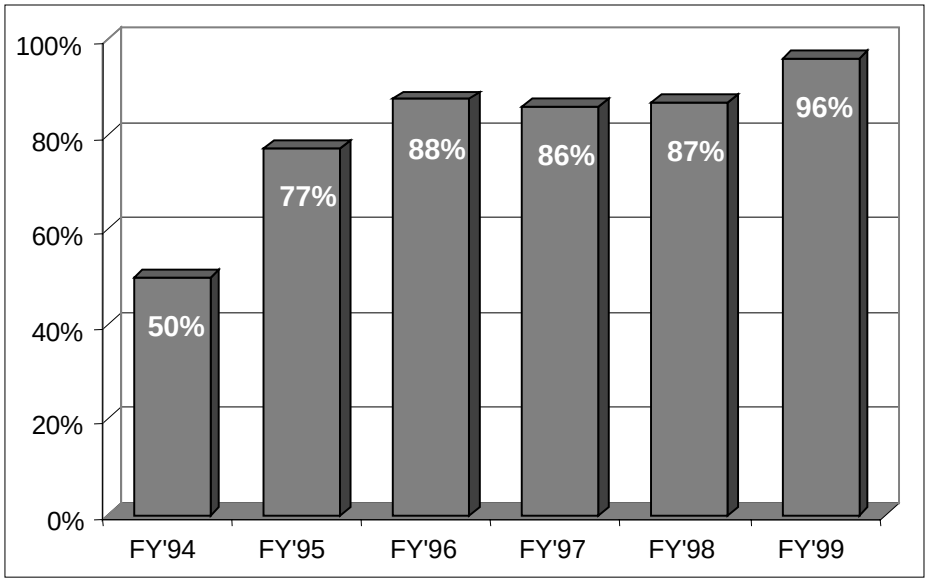

Figure 4-3.—Trend of lessons learned—favorable experiences.

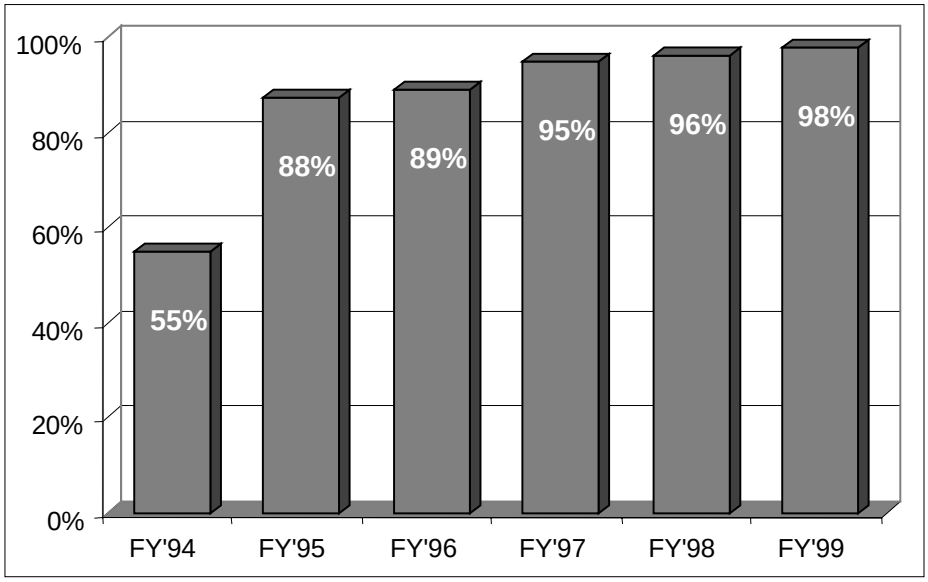

Figure 4-4.—Trend of lessons learned—no difficulties with Order 8100.7.

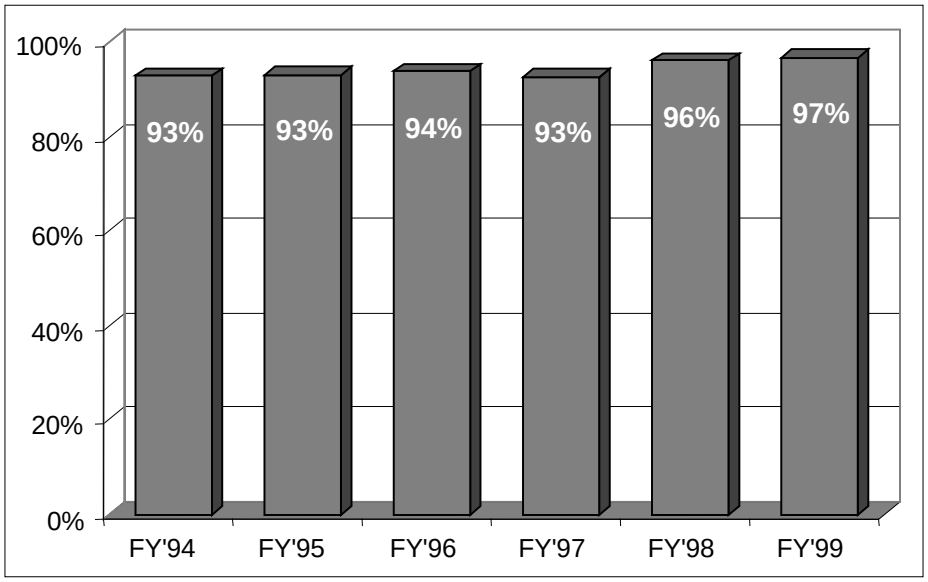

Figure 4-5.—Trend of lessons learned—evaluation completed.

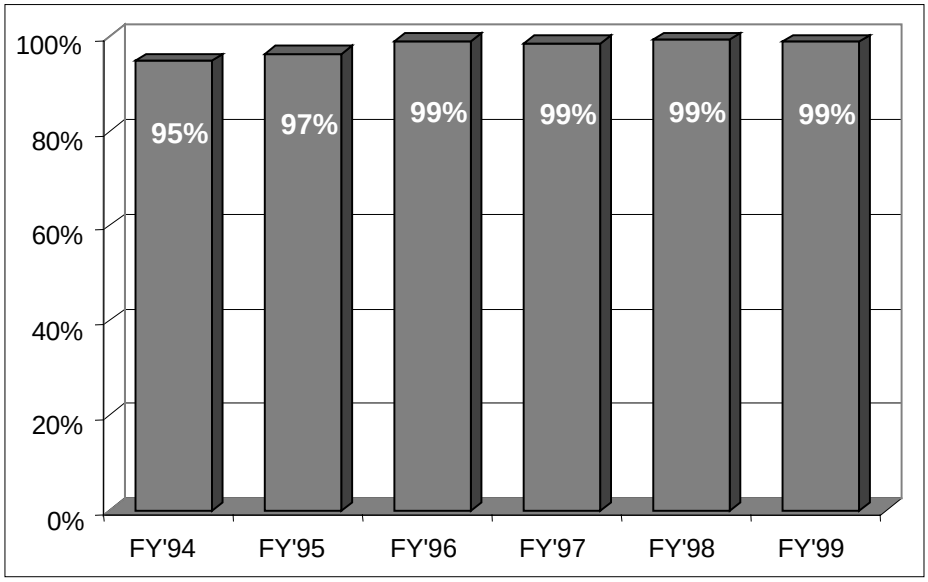

Figure 4-6.—Trend of lessons learned—no new criteria needed.

There was a marked increase in the percentage of teams reporting favorable experiences. Only two percent of the teams had problems using Order 8100.7 to conduct the evaluations. This is a slight decrease from the previous year and shows that the ACSEP teams are very comfortable using the current order. As in previous years, the evaluation teams did not, as a whole, require the need for new criteria. The percentage of teams reporting general issues and difficulties was also consistent with FY 1998 data.

Figure 4-7 presents the number of ACSEPs with system elements not completed. As with the previous year, Internal Audit ranked second in system elements not evaluated. The decision of when to evaluate or not evaluate internal audit needs to be carefully considered in light of the conclusions presented in *Section 3.9* concerning internal audit. This analysis has shown that an internal audit system not in compliance with a facility's own procedures and policies is a strong predictor of additional systemic issues elsewhere within the facility. Discovery of a discrepant internal audit program suggests that other issues may permeate the facility; i.e., what may appear on the surface to be an isolated issue could in reality be systemic in nature. However, team leaders are cautioned, once finding an internal audit system not in compliance, against focusing the evaluation with the purpose of accumulating findings and observations simply because the internal audit system was discrepant. Rather, the team leader should use this knowledge to gauge how deeply to investigate an isolated incident of noncompliance to ensure it is not really a systemic issue. Because the Internal Audit system element is such a strong indicator of overall facility compliance, the maximum benefit from evaluating an internal audit system can be obtained if it is done early in the evaluation to afford enough time to use this information.

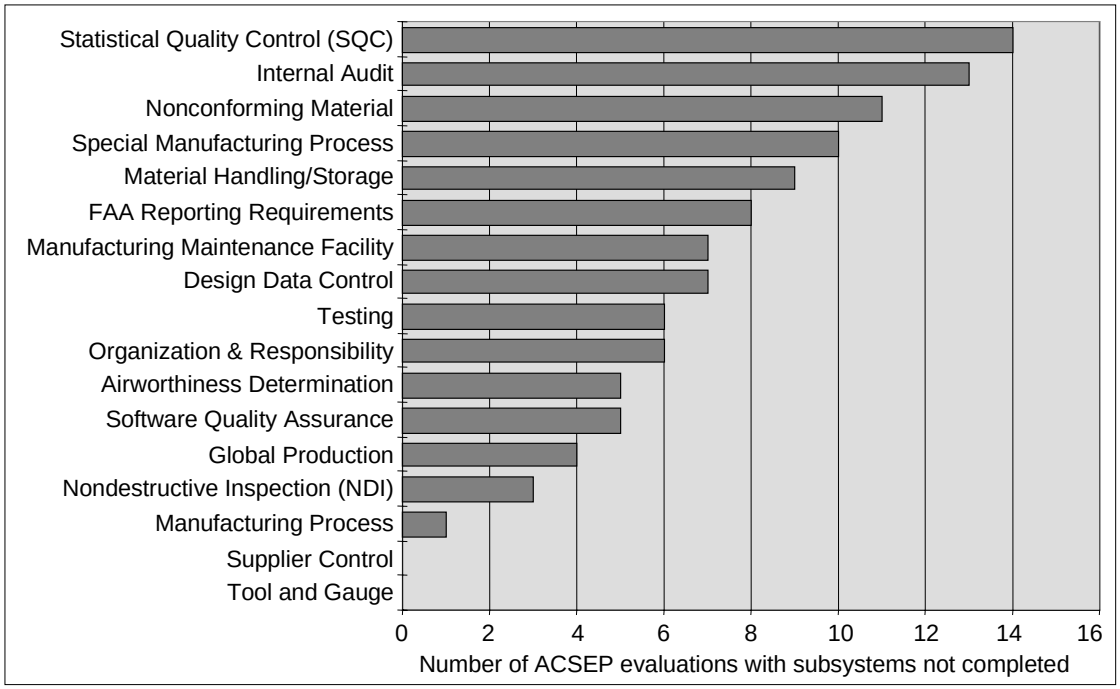

Figure 4-7.— Distribution of subsystems not evaluated.

Table 4-1 presents a detailed breakdown of comments received with the Lessons Learned. There was a slight decrease in the response to "Time scheduled at facility was too short or too long." This can be attributable to an increase in the experience of FAA personnel responsible for scheduling ACSEPs as it relates to audit duration. Also, there was a

decrease in the response to "Computer or ACSEP software issues." This can be attributed to the increased familiarity of the evaluators with the revised software introduced in FY 1998.

TABLE *4-1.—Comments received from lessons learned sheets*

General Issues/Comments	**FY'95**	**FY'96**	**FY'97**	**FY'98**	**FY'99**
Time scheduled at facility was too short or to long	5%	6%	5%	5%	3%
Computer or ACSEP software issues	3%	0%	0%	3%	1%
Logistics; no escorts or QC mgr., facility not notified	2%	0%	2%	1%	0%
QC Manual: incomplete, outdated, conflicts with other procedures	3%	1%	1%	0%	0%
Production is very low, inactive, or inappropriate for audit	7%	2%	1%	0%	1%
Management defensive/uncooperative	n/a	n/a	1%	0%	1%
ISO 9000 certification better prepared the facilities for ACSEP evaluation	1%	1%	1%	0%	1%
Recommend extending evaluation frequency	1%	1%	1%	0%	1%
Misc. other issues	2%	2%	2%	3%	1%
Difficulty with Order	**FY'95**	**FY'96**	**FY'97**	**FY'98**	**FY'99**
Criteria; add, incorrect, or system element issues	6%	5%	4%	2%	2%
ACSEP too big for facility	2%	2%	0%	1%	1%
Observations & findings; confusion with definitions	1%	1%	0%	0%	1%
Confusion about recording multiple occurrences of findings or observations	1%	1%	1%	0%	1%

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APPENDIX A
HISTORY AND BACKGROUND OF ACSEP

A1. Background

The ACSEP was developed as a result of numerous years of experience with Quality Assurance Systems Analysis Review (QASAR) audits and observations made during an interim audit program called “Operation SNAPSHOT.” Maintaining consistency with new FAA policies and regulations, with regard to the certificate management process, was also a consideration for the establishment of ACSEP. The intent was to establish a surveillance system that would meet the needs and requirements of the FAA and industry, while incorporating standardized evaluation practices and techniques consistent with the aircraft manufacturing environment and internationally recognized guidelines. The evaluation criteria were, in part, developed in conjunction with the Aerospace Industries Association and General Aviation Manufacturer's Association. By design, ACSEP will support continued operational safety in an ever changing aircraft manufacturing environment (e.g., new technologies, automation, and co-production) through recurring evaluations of facilities’ quality management systems and tracking and trending areas for improvement.

A2. Overview

ACSEP is an Aircraft Certification Service program. The Production and Airworthiness Certification Division, AIR-200, is the national focal point for the reporting of ACSEP evaluation results. Order 8100.7 provides guidance and assigns responsibility for the implementation of the ACSEP and are vital tools in assurance of the FAA's mission of continued operational safety. The program assesses the compliance of production approval holders and delegated facilities to the requirements of applicable CFR and FAA-approved data, including compliance to the procedures established to meet those requirements. It also surveys the application of standardized evaluation criteria not required by the CFR to identify national trends that may require development of new or revised regulations, policy, and guidance.

Evaluation criteria for the production approval holders are further divided into 17 system elements for detailed data collection and reporting. The 17 system elements are:

- Organization and Responsibility
- Design Data Control
- Software Quality Assurance
- Manufacturing Processes
- Special Manufacturing Processes
- Statistical Quality Control (SQC)
- Tool and Gauge
- Testing
- Nondestructive Inspection
- Supplier Control
- Nonconforming Material
- Material Handling/Storage
- Airworthiness Determination
- FAA Reporting Requirements
- Internal Audit
- Global Production
- Manufacturing Maintenance Facility

These system elements contain criteria that assess compliance to the various requirements of the CFR, FAA-approved data, and implementation of accepted industry practices. In total there are 228 evaluation criteria in the manufacturing portion of ACSEP. However, the number of evaluation criteria contained in these system elements varies and is not equally proportioned to each facility type. The amount of variation is due to the CFR requirements and industry practices for the different facility types. The 17 system elements vary in proportion from a high side of 26 evaluation criteria or 12 percent of the total for Manufacturing Processes to a low side of two evaluation criteria or 1 percent for Internal Audit (reference *figure A-1*).

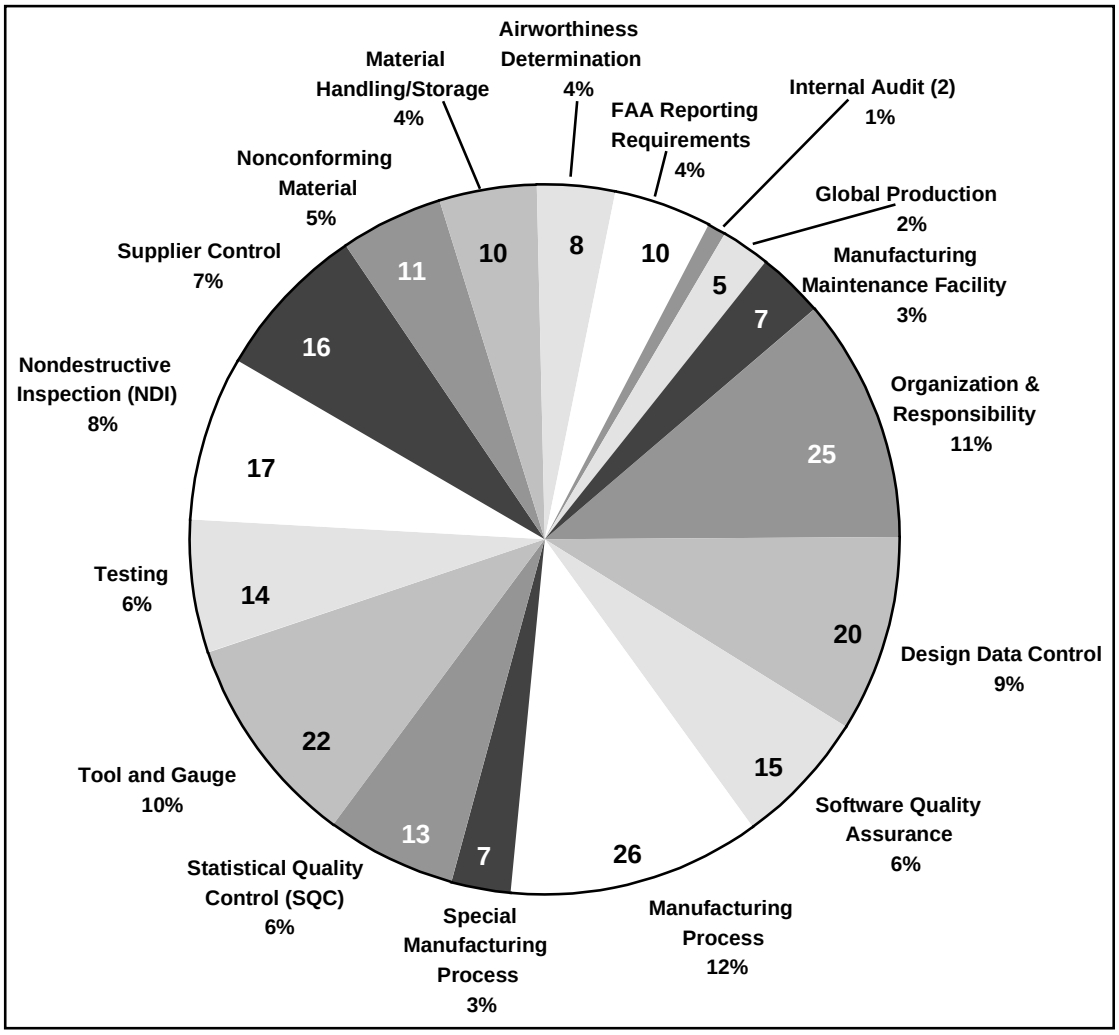

Figure A-1. —Evaluation criteria distribution within the 17 system elements of ACSEP for production approval holders.

Evaluation criteria for delegated facilities are divided into ten system elements. The ten system elements are:

- Organization and Responsibility
- Design Data Approval
- Testing
- Airworthiness Certification
- Continued Airworthiness
- Project Management
- Design Change Approval
- Conformity Inspection
- FAA Notification
- Audit

Similar to the system elements for production approval holders, these system elements contain criteria that assess compliance to the various requirements of the CFR, FAA-approved data, and implementation of accepted industry practices. In total there are 114 evaluation criteria in the delegated facility portion of ACSEP. However, the number of evaluation criteria contained in these system elements varies. The amount of variation is due to the CFR requirements and industry practices. The 10 system elements vary in proportion from a high side of 27 evaluation criteria or 23 percent of the total for Project Management to a low side of 4 evaluation criteria or 4 percent for Audit and FAA Notification (reference *figure A-2*).

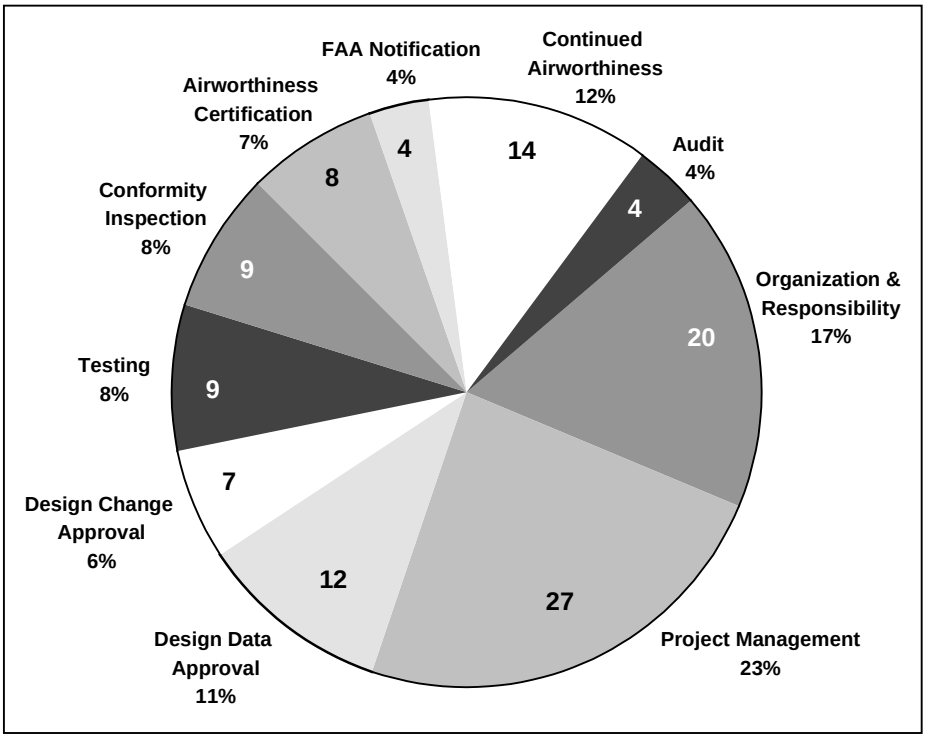

Figure A-2. —Evaluation criteria distribution within the 10 system elements of ACSEP for delegated facilities.

A3. Evaluations and Evaluators

The ACSEP utilizes teams of FAA engineering, flight test, and manufacturing inspection personnel to evaluate production approval holders and delegated facilities. Upon completion of each ACSEP evaluation, the team leader prepares a report and forwards it to the Certificate Management Office (Manufacturing Inspection Office or Aircraft Certification Office, as applicable) which provides it to the Aviation Safety Inspector (ASI) and/or the Assigned Engineer (AE) responsible for the evaluated facility. A copy of the report is also provided to AIR-200 for entry into the ACSEP database. The ACSEP database contains administrative information on facilities evaluated, status of qualified team members and team leaders, responses to rating criteria contained in the evaluation system elements, along with findings and observations noted. Additionally, the ACSEP Master Schedule, which is prepared annually, is maintained by AIR-200 together with the directorate coordinators. The scheduling database is updated and posted to a service wide electronic mail bulletin board on a monthly basis ensuring the Aircraft Certification Service offices are kept current of ACSEP evaluation cancellations, date changes, and recent additions.

The frequency at which production approval holders are scheduled for evaluation is determined by Resource Targeting. The design of Resource Targeting began in 1994 with the following objective: use a systematic, analytic approach to focus the FAA's limited resources on evaluating those facilities with the greatest potential safety impact. The main way this objective was to be met was to adjust the frequency at which facilities would be evaluated. Resource Targeting uses a process of assessing the risks and scheduling those facilities with the greatest perceived risk more frequently than facilities with less perceived risk. Annually, each approval holder is assessed with 21 safety factors and the criticality of the parts they manufacture. The 21 safety factors and part criticality are split into two aggregate factors: system strength and inherent risk. System strength is a measure of how capable the quality system is of ensuring that parts will be manufactured according to FAA-approved data. Inherent risk measures the risk that a part failure would have on continued operational safety. The collective score of the two aggregate-factors determines which of the four RT groups is assigned to the facility. Its RT group determines the frequency at which a facility is evaluated:

RT group I:	evaluated every 16 to 24 months
RT group II:	evaluated every 24 to 36 months
RT group II and IV:	evaluated every 32 to 48 months

Delegated facilities are scheduled for evaluation according to their delegation: DOA and DAS facilities are scheduled every 24 months and SFAR-36 facilities are scheduled for evaluation every 36 months.

At the conclusion of an ACSEP evaluation, a post-evaluation conference is held with the evaluated facility management and any issues, findings, and/or observations are reviewed. The ASI and/or AE responsible for facility surveillance pursue any findings that require

formal corrective action. The ASI and/or AE inform the facility of the findings and request corrective action though a Letter of Investigation, when deemed appropriate.

The ACSEP also includes a Quality Improvement Program. Data from the evaluation feedback reports and evaluation reports are used to prompt improvements in the program. Continuous improvement teams established in each directorate and in headquarters review suggestions, comments, and results of the evaluations. The directorate teams act upon improvements that can be implemented locally; improvements that affect the national program are referred to a dedicated National Continuous Improvement Team (NCIT) made up of FAA Aviation Safety Inspectors, Aerospace Engineers, and Flight Test Pilots representing the directorates and headquarters. Managers representing the Aircraft Certification Management Team (ACMT), Aircraft Certification Office Management Team (ACOMT), and Manufacturing Inspection Management Team (MIMT) are also members of the National Continuous Improvement Team (NCIT). After a comprehensive review of the data, the NCIT then recommends changes or clarification to current policy. Recommended changes are forwarded to the Aircraft Engineering Division (AIR-100) or the Production and Airworthiness Certification Division (AIR-200) for further review and possible implementation.

The AIR organization is responsible for conducting evaluator training. This is accomplished in association with the FAA Academy with AIR-200 providing instructors. These instructors are experienced national evaluation team leaders who bring real life experiences into the classroom. While one instructor presents the course materials, the other critiques the presentation/materials and notes comments from students. The critique and notes are reviewed and improvements incorporated facilitating a continuous improvement process. Additionally, issues found in the field are also integrated into the course making it even more comprehensive and continuously improving it.

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APPENDIX B
DEFINITIONS

Approved Production Inspection System (APIS) – Federal Aviation Administration (FAA) production approval issued to a manufacturer of an aircraft, aircraft engine, or propeller being manufactured under a type certificate only.

Assigned Engineer – An FAA engineer to whom the Aircraft Certification Office manager has assigned responsibility relating to ACSEP evaluations at a particular design approval facility.

Compliance – for the purposes of this report, compliance refers to a facility's business practices being consistent with published procedures and/or policies. These procedures/policies include: internal procedures/policies not requiring FAA approval, FAA-approved data, and the CFR.

Compliance Rate – the proportion of facilities whose business practices were found to be in compliance with published procedures and/or policies at the time of an ACSEP evaluation. These procedures/policies include: internal procedures/policies not requiring FAA approval, FAA-approved data, and the CFR.

Criteria – the basic element of an ACSEP evaluation. Criteria are used to plan the depth of the evaluation and to document the results of the evaluation in a standardized manner. The criteria are grouped into systems and system elements.

Delegated Facility – a facility undertaking DOA, DAS, or SFAR-36 activity.

Delegation Option Authorization (DOA) – an organization or facility authorized by the FAA to accomplish type, production, and airworthiness certification of certain products as specified in CFR § 21.231(a).

Designated Alteration Station (DAS) – an organization or facility authorized by the FAA to issue supplemental type certifications, experimental certificates, and amended standard airworthiness certificates in accordance with its FAA-approved procedures manual.

Established Industry Practice – a widely followed method of operating that achieves consistent performance of specific functions (i.e., calibration recall system, internal audit system, and statistical process control).

Facility – for this report, any production approval holder, delegation, or priority part supplier.

CFR-based Observation – an occurrence of FAA-approved data not in compliance to the Code of Federal Regulations (CFR).

Federal Aviation Regulations (FAR) – regulations listed in Title 14 (Aeronautics and Space) of the CFR.

Finding – systemic noncompliance to the CFR, FAA-approved data (or in the case of supplier facilities, the purchasing instrument), or a safety-related noncompliance.

Issue – An inconsistency between the actual operating practices of a facility and the CFR, FAA-approved data, or the facility's internal procedures.

Isolated Observation – isolated occurrence of noncompliance to the CFR or FAA-approved data.

Manufacturer's Maintenance Facility (MMF) – defined by CFR § 145.1(c) as a repair station certificate with a limited rating issued to a manufacturer based upon the production approval it holds from the FAA.

National Continuous Improvement Team (NCIT) – a dedicated national team of FAA aviation safety inspectors, aerospace engineers, flight test pilots, and managers representing the directorates and divisions chartered to review the ACSEP periodically for areas of improvement.

Noncompliance – for the purposes of this report, noncompliance refers to a facility's business practices being inconsistent with published procedures and policies at the time of the ACSEP evaluation. These procedures and/or policies include: internal procedures/policies not requiring FAA approval, FAA-approved data, and the CFR.

Noncompliance Rate – the proportion of facilities where at least one business practice was inconsistent with published procedures or policies, or any portion thereof, at the time of the ACSEP evaluation. These procedures and/or policies include: internal procedures not requiring FAA approval, FAA-approved data, and the CFR.

Nonobservance – a failure to comply with self-imposed procedures that are related to, but not required by, the applicable production approval, delegated facility approval, or quality requirements from a parent manufacturing maintenance facility.

Parts Manufacturer Approval (PMA) – an FAA production and design approval issued to manufacturers who produce replacement or modification parts, equipment, components, materials, part processes (replacement and modification, and appliances).

Principal Inspector (PI) – an FAA aviation safety inspector who has been assigned certificate management and/or surveillance responsibility for a PAH, associate facility, or priority part supplier.

Priority Part Supplier (PPS) – any person or organization (including a distributor) that furnishes priority parts (as defined in Order 8120.2A) to a PAH.

Production Approval Holder (PAH) – the holder of a PC, APIS, PMA, or TSO authorization, who controls the design and quality of a product or part thereof.

Production Certificate (PC) – an FAA production approval issued to a manufacturer of aircraft, aircraft engines, or propellers that has had its Quality Control system examined and approved by the FAA, and that holds one or more of the following: a current type certificate, rights to the benefits of a type certificate under a licensing agreement, or a supplemental type certificate.

Production Certificate Extension (PCEX) – an FAA-approved extension of a specific manufacturer's PC to another facility.

Safety Finding – safety-related noncompliance that requires immediate action.

Special Federal Aviation Regulation No. 36 (SFAR-36) – an organization or facility authorized by the FAA to approve major repairs on a product or article in accordance with its FAA-approved procedures manual.

System element – a logical grouping of several criteria into functional areas. There are 17 system elements for production approval holders and 10 system elements for delegated facilities.

System – the highest level of grouping for the ACSEP criteria. Systems comprise the individual disciplines under which the criteria fall. There are six systems: Management, Engineering, Manufacturing, Quality, Service/Product Support, and Communication with the FAA.

Systemic Issue – either a finding or a systemic observation.

Systemic Observation – systemic nonobservance to other than FAA requirements or FAA-approved data.

Technical Standard Order (TSO) a*uthorization*– an FAA design and production approval issued to a manufacturer for an article which has been found to meet a specific FAA Technical Standard Order.

APPENDIX C
CRITERIA HAVING FINDINGS OR OBSERVATIONS

C1. Production Approval Holders

This section provides the data collected during FY 1999 ACSEP evaluations conducted at production approval holders. *Tables C-1 through C-13* present the data from domestic facilities (data from the one international facility is not presented). The first three of these tables (*Tables C-1 to C-3*) present data for all approval types combined. The eight tables following (*Tables C-4 through C-11*) present data for the particular approval type specified.

The column titled "Percent of Applicable Facilities with Issues" provides the frequency of findings and/or observations being reported at those facilities where the criteria was implemented or applicable. This column of data can be used to gauge the significance of the issues at those facilities where the capability for the criteria was implemented — a facility focus as described in *Subsection 3.7.2*. In contrast, the table column titled "Percent of Facilities" (percent of all production approval holders for *Tables C-1 through C-3* or percent of a particular approval type for *Tables C-4 through C-11*) presents the frequency of facilities evaluated that had a noncompliance/nonobservance reported within the criteria. This column can be used to gauge the importance of the criteria as it affects industry as a whole — as described in *Subsection 3.7.1*.

TABLE C- 1.—Systemic findings and observations

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4P9	Completed product/part identification	35	7%	8%	8%
2	10Q1	Initial & periodic evaluations of suppliers	27	5%	6%	8%
3	4Q1	Inspection methods and plans	21	4%	5%	5%
4	10Q10	Receiving inspection	19	4%	4%	5%
5	4P4	Work instructions control manufacturing processes	18	4%	4%	5%
6	15M1	Internal auditing program	17	3%	4%	6%
7	5Q3	Accord with process specifications	15	3%	3%	8%
8	10Q8	Verification of raw material	14	3%	3%	4%
9	4Q5	Inspection records	13	3%	3%	3%
10	4M1	Operation within production limitations	12	2%	3%	3%
11	11Q1	Control of nonconforming products	11	2%	3%	3%
12	10Q5	Flow down of technical & quality requirements	10	2%	2%	3%
13	10Q2	Use of approved suppliers	10	2%	2%	3%
14	1Q4	Quality Manual	10	2%	2%	2%
14	12Q3	Storage of conforming parts	10	2%	2%	2%
15	4Q3	Issuance of inspection stamps	9	2%	2%	3%
16	2E7	Design/Technical data document control	9	2%	2%	2%
16	7Q1	Approval/inspection of tools & gauges	9	2%	2%	2%
17	11Q4	Material review record generated	8	2%	2%	2%
18	4P3	Work instructions reflect tech data	8	2%	2%	2%
19	2E2	Drawing control system	8	2%	2%	2%
20	7Q11	Control of production tooling	7	1%	2%	2%
21	11Q2	Permanent identification of scrap material	7	1%	2%	2%
22	2C1	Minor design change approval	7	1%	2%	2%
23	2E1	Design change approval	7	1%	2%	2%
24	4Q12	Completion of all inspections & tests	7	1%	2%	2%
25	5Q2	Required qualifications/approvals	6	1%	1%	4%
26	12Q5	Identification of age control products	6	1%	1%	2%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
27	1M5	Policy document review	6	1%	1%	2%
28	4P6	Familiarity with specifications	6	1%	1%	2%
29	8E1	Test procedures/instructions established	5	1%	1%	2%
30	7Q3	Tool & gauge recall system	5	1%	1%	1%
31	7Q12	Calibration records	5	1%	1%	1%
32	12Q4	Segregation of product in storage	5	1%	1%	1%
33	8E2	Control of test procedure/instruction changes	4	1%	1%	2%
34	11Q7	Corrective action monitored	4	1%	1%	1%
35	14C1	Failure reporting	4	1%	1%	1%
36	4P2	Work instructions prepared	4	1%	1%	1%
37	4E1	Accord with FAA-approved design data	4	1%	1%	1%
38	9Q1	Operator qualification	3	1%	1%	5%
39	6Q1	Statistical sampling inspection plans	3	1%	1%	2%
40	15M2	Feedback to higher-level management	3	1%	1%	1%
41	1Q3	Quality Assurance staff qualifications	3	1%	1%	1%
42	11Q5	Reinspection/retest after rework/repair	3	1%	1%	1%
43	11Q3	MRB established and operational	3	1%	1%	1%
44	7Q2	Instructions for acceptance tooling	3	1%	1%	1%
45	10Q6	Quality Assurance review of purchase documents	3	1%	1%	1%
46	7Q4	Traceability to national/international standards	3	1%	1%	1%
47	2E8	Major/minor design changes	3	1%	1%	1%
48	2E3	Technical data change approval	3	1%	1%	1%
49	1Q5	Tags, forms, etc., described	3	1%	1%	1%
50	2E9	Technical data file	3	1%	1%	1%
51	3AE1	Software Configuration Management Plan	2	0.4%	0.5%	6%
52	3AQ1	Programmed media handling/storage	2	0.4%	0.5%	6%
53	2C4	Data submittal for TSO minor changes	2	0.4%	0.5%	3%
54	16Q4	Airworthiness approval tags obtained	2	0.4%	0.5%	2%
55	5Q4	Records maintained	2	0.4%	0.5%	1%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
56	5E1	All special processes in use identified	2	0.4%	0.5%	1%
57	7Q9	Control of special processing equipment	2	0.4%	0.5%	1%
58	14C3	Submittal of quality system data changes	2	0.4%	0.5%	1%
59	4P7	Identification/control of partially accepted parts	2	0.4%	0.5%	1%
60	10Q9	Verification of shelf-life materials	2	0.4%	0.5%	1%
61	7Q16	Inaccurate tools & gauges identified	2	0.4%	0.5%	1%
62	2C2	Major design change approval	2	0.4%	0.5%	0.6%
63	12Q7	Control of product removal/issuance	2	0.4%	0.5%	1%
64	7Q14	Identification of gauges	2	0.4%	0.5%	1%
65	10Q11	Segregation of non-certificated parts	2	0.4%	0.5%	1%
66	4Q10	Inspection marking	2	0.4%	0.5%	1%
67	7Q15	Care of tools & gauges	2	0.4%	0.5%	1%
68	12Q1	Prevention of part damage/contamination	2	0.4%	0.5%	1%
69	1Q6	Record retention schedule	2	0.4%	0.5%	0%
70	10Q12	Records of receiving inspection	2	0.4%	0.5%	0%
71	8E4	Use of qualified flight test pilots	1	0.2%	0.2%	5%
72	16Q2	Control of parts from associated facilities	1	0.2%	0.2%	4%
73	17Q1	Inspection/maintenance program	1	0.2%	0.2%	2%
74	17Q2	Operation within certificate privileges	1	0.2%	0.2%	2%
75	3BQ1	Verification prior to use	1	0.2%	0.2%	2%
76	9Q9	Records of compliance	1	0.2%	0.2%	1%
76	9Q3	NDI procedures/specifications available & used	1	0.2%	0.2%	1%
77	16Q3	Export airworthiness approvals obtained	1	0.2%	0.2%	1%
77	16Q5	Documents to importing country	1	0.2%	0.2%	1%
78	6Q7	SPC control limits/subgroup selection	1	0.2%	0.2%	1%
79	6Q2	Training in sampling techniques	1	0.2%	0.2%	1%
80	10Q4	Control of buyer-furnished material	1	0.2%	0.2%	1%
81	5Q5	Action on process out of control	1	0.2%	0.2%	1%
82	5Q1	Equipment available & calibrated	1	0.2%	0.2%	1%
83	8Q3	Records of completed tests	1	0.2%	0.2%	1%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
84	14S5	Approval of service bulletins	1	0.2%	0.2%	1%
85	10Q3	Approval of supplier quality manual	1	0.2%	0.2%	1%
86	2S3	AD/safety-related design changes to users	1	0.2%	0.2%	1%
86	7Q8	Use of personal gauges	1	0.2%	0.2%	1%
87	2S1	Service/Product Support review of design changes	1	0.2%	0.2%	0.5%
88	2S2	Distribution of Inst. for Continued Airworthiness changes	1	0.2%	0.2%	0.5%
89	7Q18	Action on product measured by SOT gauge	1	0.2%	0.2%	0.4%
90	10C2	New suppliers/first articles	1	0.2%	0.2%	0.4%
91	12Q2	Special environmental controls	1	0.2%	0.2%	0.4%
92	8Q1	QA review of test instructions	1	0.2%	0.2%	0.4%
93	14S2	Record of service difficulties	1	0.2%	0.2%	0.4%
94	7E1	Engineering participation in selection	1	0.2%	0.2%	0.4%
95	14S3	Investigation/corrective action	1	0.2%	0.2%	0.4%
96	11C1	Major changes approved	1	0.2%	0.2%	0.3%
97	12P1	Manufacturing review of handling specifications, etc.	1	0.2%	0.2%	0.3%
98	11E1	Engineering review for major/minor changes	1	0.2%	0.2%	0.3%
99	4Q4	Inspection stamps & damage to material	1	0.2%	0.2%	0.3%
100	11Q6	Corrective action required	1	0.2%	0.2%	0.3%
101	11M1	Management review of data	1	0.2%	0.2%	0.3%
102	4Q11	Inspection before closure	1	0.2%	0.2%	0.3%
103	4P5	Work instruction revision approval	1	0.2%	0.2%	0.3%
104	4Q8	Traceable components identified	1	0.2%	0.2%	0.3%
105	7Q7	Accuracy of inspection & test equipment	1	0.2%	0.2%	0.3%
106	1M6	Policies/procedures availability	1	0.2%	0.2%	0.3%
107	12Q8	Conforming products packaged & shipped	1	0.2%	0.2%	0.3%
108	2E6	Storage of design documents	1	0.2%	0.2%	0.2%
		TOTAL	**512**			

TABLE C- 2.—Isolated observations

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	11Q1	Control of nonconforming products	6	5%	1%	2%
2	7Q1	Approval/inspection of tools & gauges	6	5%	1%	2%
3	4P9	Completed product/part identification	6	5%	1%	1%
4	12Q5	Identification of age control products	5	4%	1%	2%
5	2E1	Design change approval	4	3%	1%	1%
6	10Q10	Receiving inspection	4	3%	1%	1%
7	9Q3	NDI procedures/specifications available & used	3	3%	1%	4%
8	12Q2	Special environmental controls	3	3%	1%	1%
9	15M1	Internal auditing program	3	3%	1%	1%
10	8E1	Test procedures/instructions established	3	3%	1%	1%
11	11Q3	MRB established and operational	3	3%	1%	1%
12	4P5	Work instruction revision approval	3	3%	1%	1%
13	7Q12	Calibration records	3	3%	1%	1%
14	4P4	Work instructions control manufacturing processes	3	3%	1%	1%
15	10Q2	Use of approved suppliers	3	3%	1%	1%
16	4Q12	Completion of all inspections & tests	3	3%	1%	1%
17	2E2	Drawing control system	3	3%	1%	1%
18	5Q2	Required qualifications/approvals	2	2%	0.5%	1%
19	7Q11	Control of production tooling	2	2%	0.5%	1%
20	10Q9	Verification of shelf-life materials	2	2%	0.5%	1%
21	11Q6	Corrective action required	2	2%	0.5%	1%
22	11Q4	Material review record generated	2	2%	0.5%	1%
23	7Q2	Instructions for acceptance tooling	2	2%	0.5%	1%
24	7Q3	Tool & gauge recall system	2	2%	0%	1%
24	10Q5	Flow down of technical & quality requirements	2	2%	0%	1%
25	2E7	Design/Technical data document control	2	2%	0.5%	1%
26	12Q1	Prevention of part damage/contamination	2	2%	0.5%	1%
27	4Q1	Inspection methods and plans	2	2%	0.5%	0%
28	12Q4	Segregation of product in storage	2	2%	0.5%	0%

TABLE C- 2.—Isolated observations—Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
29	4Q5	Inspection records	2	2%	0.5%	0%
30	10Q12	Records of receiving inspection	2	2%	0.5%	0%
31	13C3	Cancellation of certifications for passed title	1	1%	0.2%	7%
32	9Q14	Critical penetrant parameters identified	1	1%	0.2%	2%
33	3BE2	Change documentation and approval	1	1%	0.2%	2%
33	9Q9	Records of compliance	1	1%	0.2%	1%
34	6Q2	Training in sampling techniques	1	1%	0.2%	1%
35	6Q1	Statistical sampling inspection plans	1	1%	0.2%	1%
36	5Q1	Equipment available & calibrated	1	1%	0.2%	1%
37	14C5	Coordination of service bulletins, etc.	1	1%	0.2%	1%
38	8Q4	Retest after adjustment/rework	1	1%	0.2%	0.5%
39	15M2	Feedback to higher-level management	1	1%	0.2%	0.4%
40	8E2	Control of test procedure/instruction changes	1	1%	0.2%	0.4%
41	14C3	Submittal of quality system data changes	1	1%	0.2%	0.4%
42	11C1	Major changes approved	1	1%	0.2%	0.3%
43	10Q1	Initial & periodic evaluations of suppliers	1	1%	0.2%	0.3%
43	11Q2	Permanent identification of scrap material	1	1%	0.2%	0.3%
44	2C1	Minor design change approval	1	1%	0.2%	0.3%
45	12Q7	Control of product removal/issuance	1	1%	0.2%	0%
46	1Q1	Quality organizations described	1	1%	0.2%	0.3%
47	7Q14	Identification of gauges	1	1%	0.2%	0.3%
48	4Q9	Traceability to raw material	1	1%	0.2%	0.3%
49	2E8	Major/minor design changes	1	1%	0.2%	0.3%
50	12Q3	Storage of conforming parts	1	1%	0.2%	0.2%
51	1Q6	Record retention schedule	1	1%	0.2%	0.2%
		TOTAL	**115**			

TABLE C- 3.—CFR-based observations

Rank	Criteria	Description	Number of CFR-based Observations	Percent of Total CFR-based Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	5Q3	Accord with process specifications	3	16%	1%	2%
2	3AE1	Software Configuration Management Plan	1	5%	0.2%	3%
3	10C3	Direct shipment	1	5%	0.2%	2%
4	6Q1	Statistical sampling inspection plans	1	5%	0.2%	1%
5	5Q4	Records maintained	1	5%	0.2%	1%
6	13E1	AD incorporation	1	5%	0.2%	0.5%
7	2S2	Distribution of Inst. for Continued Airworthiness changes	1	5%	0.2%	0.5%
8	4Q2	Location of inspection stations	1	5%	0.2%	0.3%
9	14C1	Failure reporting	1	5%	0.2%	0.3%
10	10Q6	Quality Assurance review of purchase documents	1	5%	0.2%	0.3%
11	11Q2	Permanent identification of scrap material	1	5%	0.2%	0.3%
12	1Q1	Quality organizations described	1	5%	0.2%	0.3%
13	10Q8	Verification of raw material	1	5%	0.2%	0.3%
14	4Q1	Inspection methods and plans	1	5%	0.2%	0.2%
15	2E2	Drawing control system	1	5%	0.2%	0.2%
16	4P9	Completed product/part identification	1	5%	0.2%	0.2%
17	4M1	Operation within production limitations	1	5%	0.2%	0.2%
		Total	**19**			

TABLE C- 4.—Systemic findings and observations–APIS holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for APIS Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4Q11	Inspection before closure	1	5%	50%	100%
1	4Q3	Issuance of inspection stamps	1	5%	50%	100%
1	10Q9	Verification of shelf-life materials	1	5%	50%	100%
1	15M1	Internal auditing program	1	5%	50%	100%
2	1M6	Policies/procedures availability	1	5%	50%	50%
2	1Q3	Quality Assurance staff qualifications	1	5%	50%	50%
2	4P2	Work instructions prepared	1	5%	50%	50%
2	4P3	Work instructions reflect tech data	1	5%	50%	50%
2	4P4	Work instructions control manufacturing processes	1	5%	50%	50%
2	4P6	Familiarity with specifications	1	5%	50%	50%
2	4P9	Completed product/part identification	1	5%	50%	50%
2	4Q1	Inspection methods and plans	1	5%	50%	50%
2	4Q12	Completion of all inspections & tests	1	5%	50%	50%
2	4Q5	Inspection records	1	5%	50%	50%
2	10Q10	Receiving inspection	1	5%	50%	50%
2	11M1	Management review of data	1	5%	50%	50%
2	11Q4	Material review record generated	1	5%	50%	50%
2	11Q7	Corrective action monitored	1	5%	50%	50%
2	12Q3	Storage of conforming parts	1	5%	50%	50%
2	14C1	Failure reporting	1	5%	50%	50%
2	14S2	Record of service difficulties	1	5%	50%	50%
		TOTAL	**21**			

TABLE C- 5.—Systemic findings and observations–PC holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4P4	Work instructions control manufacturing processes	5	6%	20%	20%
2	10Q10	Receiving inspection	4	5%	16%	16%
3	5Q2	Required qualifications/approvals	3	4%	12%	14%
3	15M1	Internal auditing program	3	4%	12%	14%
4	4Q5	Inspection records	3	4%	12%	12%
5	5Q3	Accord with process specifications	2	2%	8%	10%
6	10Q5	Flow down of technical & quality requirements	2	2%	8%	9%
7	8E1	Test procedures/instructions established	2	2%	8%	9%
7	8E2	Control of test procedure/instruction changes	2	2%	8%	9%
7	11Q2	Permanent identification of scrap material	2	2%	8%	9%
8	2E7	Design/Technical data document control	2	2%	8%	8%
8	4Q3	Issuance of inspection stamps	2	2%	8%	8%
8	11Q4	Material review record generated	2	2%	8%	8%
9	4Q1	Inspection methods and plans	2	2%	8%	8%
9	4P6	Familiarity with specifications	2	2%	8%	8%
9	10Q8	Verification of raw material	2	2%	8%	8%
9	12Q3	Storage of conforming parts	2	2%	8%	8%
10	8E4	Use of qualified flight test pilots	1	1%	4%	8%
11	3BQ1	Verification prior to use	1	1%	4%	7%
12	6Q1	Statistical sampling inspection plans	1	1%	4%	7%
12	16Q4	Airworthiness approval tags obtained	1	1%	4%	7%
13	9Q3	NDI procedures/specifications available & used	1	1%	4%	6%
14	4P7	Identification/control of partially accepted parts	1	1%	4%	5%
14	7Q18	Action on product measured by SOT gauge	1	1%	4%	5%
15	5Q1	Equipment available & calibrated	1	1%	4%	5%
15	5Q5	Action on process out of control	1	1%	4%	5%
15	12Q2	Special environmental controls	1	1%	4%	5%
16	5Q4	Records maintained	1	1%	4%	5%

TABLE C- 5.—Systemic findings and observations–PC holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
16	10Q1	Initial & periodic evaluations of suppliers	1	1%	4%	5%
17	1Q3	Quality Assurance staff qualifications	1	1%	4%	5%
17	2C1	Minor design change approval	1	1%	4%	5%
17	11Q7	Corrective action monitored	1	1%	4%	5%
17	12P1	Manufacturing review of handling specifications, etc.	1	1%	4%	5%
17	14C1	Failure reporting	1	1%	4%	5%
18	1M5	Policy document review	1	1%	4%	4%
18	7Q2	Instructions for acceptance tooling	1	1%	4%	4%
18	10Q2	Use of approved suppliers	1	1%	4%	4%
18	11Q6	Corrective action required	1	1%	4%	4%
18	11Q5	Reinspection/retest after rework/repair	1	1%	4%	4%
18	12Q5	Identification of age control products	1	1%	4%	4%
18	14C3	Submittal of quality system data changes	1	1%	4%	4%
19	2E2	Drawing control system	1	1%	4%	4%
19	7Q15	Care of tools & gauges	1	1%	4%	4%
19	11Q1	Control of nonconforming products	1	1%	4%	4%
19	12Q7	Control of product removal/issuance	1	1%	4%	4%
19	12Q1	Prevention of part damage/contamination	1	1%	4%	4%
20	2E1	Design change approval	1	1%	4%	4%
20	4E1	Accord with FAA-approved design data	1	1%	4%	4%
20	4P3	Work instructions reflect tech data	1	1%	4%	4%
20	4P9	Completed product/part identification	1	1%	4%	4%
20	4Q8	Traceable components identified	1	1%	4%	4%
20	7Q3	Tool & gauge recall system	1	1%	4%	4%
20	7Q12	Calibration records	1	1%	4%	4%
20	7Q1	Approval/inspection of tools & gauges	1	1%	4%	4%
20	10Q11	Segregation of non-certificated parts	1	1%	4%	4%

TABLE C- 5.—Systemic findings and observations–PC holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
20	12Q4	Segregation of product in storage	1	1%	4%	4%
		TOTAL	**81**			

TABLE C- 6.—Systemic findings and observations–PMA holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4P9	Completed product/part identification	30	10%	9%	9%
2	10Q1	Initial & periodic evaluations of suppliers	19	6%	5%	7%
3	4Q1	Inspection methods and plans	13	4%	4%	4%
4	10Q8	Verification of raw material	12	4%	3%	4%
5	5Q3	Accord with process specifications	9	3%	3%	6%
6	15M1	Internal auditing program	9	3%	3%	4%
7	4P4	Work instructions control manufacturing processes	9	3%	3%	3%
8	10Q10	Receiving inspection	9	3%	3%	3%
9	7Q1	Approval/inspection of tools & gauges	8	3%	2%	3%
10	11Q1	Control of nonconforming products	8	3%	2%	3%
11	4Q5	Inspection records	8	3%	2%	2%
12	4M1	Operation within production limitations	8	3%	2%	2%
13	7Q11	Control of production tooling	6	2%	2%	3%
14	2C1	Minor design change approval	6	2%	2%	2%
15	10Q2	Use of approved suppliers	6	2%	2%	2%
16	2E1	Design change approval	6	2%	2%	2%
17	1Q4	Quality Manual	6	2%	2%	2%
18	11Q2	Permanent identification of scrap material	5	2%	1%	2%
19	2E7	Design/Technical data document control	5	2%	1%	2%
20	2E2	Drawing control system	5	2%	1%	1%
21	1M5	Policy document review	4	1%	1%	1%
22	4Q3	Issuance of inspection stamps	4	1%	1%	1%
23	4P3	Work instructions reflect tech data	4	1%	1%	1%
24	4Q12	Completion of all inspections & tests	4	1%	1%	1%
25	12Q4	Segregation of product in storage	4	1%	1%	1%
26	12Q3	Storage of conforming parts	4	1%	1%	1%
27	9Q1	Operator qualification	3	1%	1%	8%
28	5Q2	Required qualifications/approvals	3	1%	1%	2%
29	11Q3	MRB established and operational	3	1%	1%	1%

TABLE C- 6.—Systemic findings and observations–PMA holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
30	12Q5	Identification of age control products	3	1%	1%	1%
31	10Q6	Quality Assurance review of purchase documents	3	1%	1%	1%
32	10Q5	Flow down of technical & quality requirements	3	1%	1%	1%
33	7Q12	Calibration records	3	1%	1%	1%
34	2E3	Technical data change approval	3	1%	1%	1%
35	1Q5	Tags, forms, etc., described	3	1%	1%	1%
36	6Q1	Statistical sampling inspection plans	2	1%	1%	2%
37	5E1	All special processes in use identified	2	1%	1%	1%
38	8E1	Test procedures/instructions established	2	1%	1%	1%
39	11Q5	Reinspection/retest after rework/repair	2	1%	1%	1%
40	11Q4	Material review record generated	2	1%	1%	1%
40	14C1	Failure reporting	2	1%	1%	1%
41	2C2	Major design change approval	2	1%	1%	1%
42	7Q14	Identification of gauges	2	1%	1%	1%
43	7Q4	Traceability to national/international standards	2	1%	1%	1%
44	4Q10	Inspection marking	2	1%	1%	1%
45	2E8	Major/minor design changes	2	1%	1%	1%
45	4P2	Work instructions prepared	2	1%	1%	1%
46	4E1	Accord with FAA-approved design data	2	1%	1%	1%
47	2C4	Data submittal for TSO minor changes	1	0%	0.3%	11%
48	16Q2	Control of parts from associated facilities	1	0%	0.3%	6%
49	17Q1	Inspection/maintenance program	1	0%	0.3%	3%
50	17Q2	Operation within certificate privileges	1	0%	0.3%	3%
51	9Q9	Records of compliance	1	0%	0.3%	2%
52	16Q4	Airworthiness approval tags obtained	1	0%	0.3%	2%
53	6Q2	Training in sampling techniques	1	0%	0.3%	1%
54	5Q4	Records maintained	1	0%	0.3%	1%
55	14S5	Approval of service bulletins	1	0%	0.3%	1%
56	10Q3	Approval of supplier quality manual	1	0%	0.3%	1%

TABLE C- 6.—Systemic findings and observations–PMA holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
57	2S3	AD/safety-related design changes to users	1	0%	0.3%	1%
58	2S1	Service/Product Support review of design changes	1	0%	0.3%	1%
59	7Q9	Control of special processing equipment	1	0%	0.3%	1%
60	8Q1	QA review of test instructions	1	0%	0.3%	1%
61	8E2	Control of test procedure/instruction changes	1	0%	0.3%	1%
62	14C3	Submittal of quality system data changes	1	0%	0.3%	0.5%
63	11C1	Major changes approved	1	0%	0.3%	0.4%
64	11Q7	Corrective action monitored	1	0%	0.3%	0.4%
65	11E1	Engineering review for major/minor changes	1	0%	0.3%	0.4%
66	10Q9	Verification of shelf-life materials	1	0%	0.3%	0.4%
67	7Q2	Instructions for acceptance tooling	1	0%	0.3%	0.4%
68	7Q16	Inaccurate tools & gauges identified	1	0%	0.3%	0.4%
69	7Q3	Tool & gauge recall system	1	0%	0.3%	0.4%
70	12Q7	Control of product removal/issuance	1	0%	0.3%	0.3%
71	7Q7	Accuracy of inspection & test equipment	1	0%	0.3%	0.3%
72	7Q15	Care of tools & gauges	1	0%	0.3%	0.3%
73	4P6	Familiarity with specifications	1	0%	0.3%	0.3%
74	12Q1	Prevention of part damage/contamination	1	0%	0.3%	0.3%
75	1Q6	Record retention schedule	1	0%	0.3%	0.3%
76	2E6	Storage of design documents	1	0%	0.3%	0.3%
77	10Q12	Records of receiving inspection	1	0%	0.3%	0.3%
		TOTAL	**295**			

TABLE C- 7.—Systemic findings and observations–TSO authorization holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for TSOA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	10Q1	Initial & periodic evaluations of suppliers	7	6%	14%	16%
2	10Q5	Flow down of technical & quality requirements	5	4%	10%	11%
3	4Q1	Inspection methods and plans	5	4%	10%	10%
3	10Q10	Receiving inspection	5	4%	10%	10%
4	5Q3	Accord with process specifications	4	3%	8%	18%
5	15M1	Internal auditing program	4	3%	8%	11%
6	4M1	Operation within production limitations	4	3%	8%	8%
7	1Q4	Quality Manual	4	3%	8%	8%
8	15M2	Feedback to higher-level management	3	3%	6%	9%
9	7Q3	Tool & gauge recall system	3	3%	6%	7%
9	11Q4	Material review record generated	3	3%	6%	7%
10	10Q2	Use of approved suppliers	3	3%	6%	6%
11	12Q3	Storage of conforming parts	3	3%	6%	6%
12	2E9	Technical data file	3	3%	6%	6%
12	4P4	Work instructions control manufacturing processes	3	3%	6%	6%
13	4P9	Completed product/part identification	3	3%	6%	6%
14	3AE1	Software Configuration Management Plan	2	2%	4%	25%
14	3AQ1	Programmed media handling/storage	2	2%	4%	25%
15	12Q5	Identification of age control products	2	2%	4%	5%
16	4Q3	Issuance of inspection stamps	2	2%	4%	5%
17	4P3	Work instructions reflect tech data	2	2%	4%	4%
18	2E7	Design/Technical data document control	2	2%	4%	4%
19	4P6	Familiarity with specifications	2	2%	4%	4%
19	11Q1	Control of nonconforming products	2	2%	4%	4%
20	2E2	Drawing control system	2	2%	4%	4%

TABLE C- 7.—Systemic findings and observations–TSO authorization holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for TSOA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
21	4Q12	Completion of all inspections & tests	2	2%	4%	4%
22	16Q3	Export airworthiness approvals obtained	1	1%	2%	9%
22	16Q5	Documents to importing country	1	1%	2%	9%
23	6Q7	SPC control limits/subgroup selection	1	1%	2%	8%
24	10Q4	Control of buyer-furnished material	1	1%	2%	6%
25	7Q8	Use of personal gauges	1	1%	2%	5%
26	7Q9	Control of special processing equipment	1	1%	2%	3%
26	8Q3	Records of completed tests	1	1%	2%	3%
27	10C2	New suppliers/first articles	1	1%	2%	3%
28	14S3	Investigation/corrective action	1	1%	2%	3%
29	2S2	Distribution of Inst. for Continued Airworthiness changes	1	1%	2%	3%
30	7Q11	Control of production tooling	1	1%	2%	3%
31	4P7	Identification/control of partially accepted parts	1	1%	2%	3%
31	11Q7	Corrective action monitored	1	1%	2%	3%
32	7E1	Engineering participation in selection	1	1%	2%	3%
33	4Q4	Inspection stamps & damage to material	1	1%	2%	3%
34	7Q2	Instructions for acceptance tooling	1	1%	2%	2%
35	1M5	Policy document review	1	1%	2%	2%
35	1Q3	Quality Assurance staff qualifications	1	1%	2%	2%
36	7Q16	Inaccurate tools & gauges identified	1	1%	2%	2%
36	8E2	Control of test procedure/instruction changes	1	1%	2%	2%
37	4P5	Work instruction revision approval	1	1%	2%	2%
38	2C4	Data submittal for TSO minor changes	1	1%	2%	2%
38	7Q4	Traceability to national/international standards	1	1%	2%	2%
38	8E1	Test procedures/instructions established	1	1%	2%	2%

TABLE C- 7.—Systemic findings and observations–TSO authorization holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for TSOA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
39	4Q5	Inspection records	1	1%	2%	2%
39	7Q12	Calibration records	1	1%	2%	2%
39	10Q11	Segregation of non-certificated parts	1	1%	2%	2%
39	12Q8	Conforming products packaged & shipped	1	1%	2%	2%
40	4E1	Accord with FAA-approved design data	1	1%	2%	2%
40	4P2	Work instructions prepared	1	1%	2%	2%
41	2E8	Major/minor design changes	1	1%	2%	2%
41	10Q12	Records of receiving inspection	1	1%	2%	2%
42	1Q6	Record retention schedule	1	1%	2%	2%
		TOTAL	**115**			

TABLE C- 8.—Isolated observations–APIS holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for APIS Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	2E2	Drawing control system	1	14%	50%	50%
1	4P5	Work instruction revision approval	1	14%	50%	50%
1	7Q11	Control of production tooling	1	14%	50%	50%
1	8E1	Test procedures/instructions established	1	14%	50%	50%
1	8E2	Control of test procedure/instruction changes	1	14%	50%	50%
1	11Q1	Control of nonconforming products	1	14%	50%	50%
1	11Q3	MRB established and operational	1	14%	50%	50%
		TOTAL	**7**			

TABLE C- 9.—Isolated observations–PC holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	11Q1	Control of nonconforming products	3	7%	12%	13%
2	5Q2	Required qualifications/approvals	2	5%	8%	10%
2	15M1	Internal auditing program	2	5%	8%	10%
3	10Q2	Use of approved suppliers	2	5%	8%	9%
3	12Q5	Identification of age control products	2	5%	8%	9%
4	2E2	Drawing control system	2	5%	8%	8%
4	12Q1	Prevention of part damage/contamination	2	5%	8%	8%
5	7Q12	Calibration records	2	5%	8%	8%
5	10Q10	Receiving inspection	2	5%	8%	8%
6	13C3	Cancellation of certifications for passed title	1	2%	4%	13%
7	3BE2	Change documentation and approval	1	2%	4%	7%
8	6Q1	Statistical sampling inspection plans	1	2%	4%	7%
9	9Q14	Critical penetrant parameters identified	1	2%	4%	6%
10	9Q9	Records of compliance	1	2%	4%	6%
11	9Q3	NDI procedures/specifications available & used	1	2%	4%	6%
12	14C5	Coordination of service bulletins, etc.	1	2%	4%	5%
13	10Q1	Initial & periodic evaluations of suppliers	1	2%	4%	5%
14	10Q5	Flow down of technical & quality requirements	1	2%	4%	5%
15	7Q2	Instructions for acceptance tooling	1	2%	4%	4%
15	10Q9	Verification of shelf-life materials	1	2%	4%	4%
15	11Q2	Permanent identification of scrap material	1	2%	4%	4%
15	11Q6	Corrective action required	1	2%	4%	4%
15	14C3	Submittal of quality system data changes	1	2%	4%	4%
16	1Q6	Record retention schedule	1	2%	4%	4%
16	4P5	Work instruction revision approval	1	2%	4%	4%

TABLE C- 9.— Isolated observations–PC holders only —Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
16	10Q12	Records of receiving inspection	1	2%	4%	4%
16	11Q4	Material review record generated	1	2%	4%	4%
16	12Q7	Control of product removal/issuance	1	2%	4%	4%
17	1Q1	Quality organizations described	1	2%	4%	4%
17	4P4	Work instructions control manufacturing processes	1	2%	4%	4%
17	4Q1	Inspection methods and plans	1	2%	4%	4%
17	4Q5	Inspection records	1	2%	4%	4%
17	7Q3	Tool & gauge recall system	1	2%	4%	4%
17	12Q3	Storage of conforming parts	1	2%	4%	4%
		TOTAL	**44**			

TABLE C- 10.— Isolated observations–PMA holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4P9	Completed product/part identification	6	15%	2%	2%
2	7Q1	Approval/inspection of tools & gauges	3	8%	1%	1%
3	2E1	Design change approval	3	8%	1%	1%
4	4Q12	Completion of all inspections & tests	3	8%	1%	1%
5	9Q3	NDI procedures/specifications available & used	2	5%	1%	4%
6	12Q2	Special environmental controls	2	5%	1%	1%
7	12Q5	Identification of age control products	2	5%	1%	1%
8	12Q4	Segregation of product in storage	2	5%	1%	1%
9	10Q10	Receiving inspection	2	5%	1%	1%
10	7Q11	Control of production tooling	1	3%	0%	0%
11	11C1	Major changes approved	1	3%	0%	0%
12	11Q3	MRB established and operational	1	3%	0%	0%
13	10Q9	Verification of shelf-life materials	1	3%	0%	0%
14	11Q6	Corrective action required	1	3%	0%	0%
15	11Q4	Material review record generated	1	3%	0%	0%
16	7Q2	Instructions for acceptance tooling	1	3%	0%	0%
17	4P5	Work instruction revision approval	1	3%	0%	0%
18	7Q3	Tool & gauge recall system	1	3%	0%	0%
19	10Q5	Flow down of technical & quality requirements	1	3%	0%	0%
20	2C1	Minor design change approval	1	3%	0%	0%
21	7Q14	Identification of gauges	1	3%	0%	0%
22	2E8	Major/minor design changes	1	3%	0%	0%
23	11Q1	Control of nonconforming products	1	3%	0%	0%
24	4Q1	Inspection methods and plans	1	3%	0%	0%
		TOTAL	**40**			

TABLE C- 11.— Isolated observations–TSO authorization holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for TSOA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	7Q1	Approval/inspection of tools & gauges	3	13%	6%	6%
2	2E7	Design/Technical data document control	2	8%	4%	4%
2	8E1	Test procedures/instructions established	2	8%	4%	4%
3	4P4	Work instructions control manufacturing processes	2	8%	4%	4%
4	6Q2	Training in sampling techniques	1	4%	2%	7%
5	5Q1	Equipment available & calibrated	1	4%	2%	5%
6	12Q2	Special environmental controls	1	4%	2%	3%
7	15M2	Feedback to higher-level management	1	4%	2%	3%
8	15M1	Internal auditing program	1	4%	2%	3%
9	8Q4	Retest after adjustment/rework	1	4%	2%	3%
10	12Q5	Identification of age control products	1	4%	2%	2%
11	11Q3	MRB established and operational	1	4%	2%	2%
12	10Q2	Use of approved suppliers	1	4%	2%	2%
13	4Q5	Inspection records	1	4%	2%	2%
13	4Q9	Traceability to raw material	1	4%	2%	2%
13	7Q12	Calibration records	1	4%	2%	2%
13	11Q1	Control of nonconforming products	1	4%	2%	2%
14	2E1	Design change approval	1	4%	2%	2%
15	10Q12	Records of receiving inspection	1	4%	2%	2%
		TOTAL	**24**			

C2. Delegated Facilities

This section provides the data collected during FY 1999 ACSEP evaluations conducted at DAS, SFAR-36, and DOA facilities. The first two tables (*Table C-12 and C-13*) present data for all delegated facilities combined. The following six tables (*Tables C-14 through C-16*) present data from the individual delegation types.

TABLE C- 12.—Systemic findings and observations – delegated facilities

Rank	Criteria	Name	Number Of Systemic Findings And Observations	Percent Of All Systemic Findings And Observations	Percent Of All Facilities That Had Systemic Findings And Observations
1	8D1	Submittal of required information to FAA	3	16%	23%
2	3D5	Technical/repair data is approved	2	11%	18%
3	9D9	Record of reported service difficulties maintained	2	11%	25%
4	1D10	Delegation inspection and airworthiness org. described	1	5%	10%
5	1D16	Training of delegated facility staff	1	5%	11%
6	1D2	Current Procedure Manual/Handbook	1	5%	8%
6	1D4	Operation within approved delegation authority	1	5%	8%
6	1D6	Continues to meet criteria for holding authorization	1	5%	8%
7	2D1	Certification basis established	1	5%	10%
8	2D2	Use of latest airworthiness standards	1	5%	17%
9	2D20	Approval/control of AFM/AFMS	1	5%	14%
10	4D2	Major/minor determination	1	5%	8%
11	5D1	Approval of certification tests	1	5%	11%
11	6D2	Conformity inspections documented	1	5%	11%
12	9D12	Approval of service bulletins and maint. manuals	1	5%	14%
		TOTAL	**19**		

TABLE C- 13.—Isolated findings and observations – delegated facilities

Rank	Criteria	Name	Number Of Isolated Observations	Percent Of All Isolated Observations	Percent Of All Facilities That Had Isolated Observations
1	2D21	TIR/STIR to document conformity, inspection, and tests	1	25%	13%
2	2D27	Documentation/approval of type design data	1	25%	9%
3	3D2	Use of approved documents and forms	1	25%	8%
4	3D3	Classification of data being approved	1	25%	8%
		TOTAL	**4**		

TABLE C- 14.—Systemic findings and observations – DAS facilities

Rank	Criteria	Name	Number Of Systemic Findings And Observations	Percent Of All Systemic Findings And Observations for DAS facilities	Percent Of All DAS Facilities That Had Systemic Findings And Observations
1	8D1	Submittal of required information to FAA	3	18%	38%
2	3D5	Technical/repair data is approved	2	12%	33%
3	9D9	Record of reported service difficulties maintained	2	12%	40%
4	1D10	Delegation inspection and airworthiness org. described	1	6%	13%
4	1D2	Current Procedure Manual/Handbook	1	6%	13%
4	1D4	Operation within approved delegation authority	1	6%	13%
4	1D6	Continues to meet criteria for holding authorization	1	6%	13%
5	2D2	Use of latest airworthiness standards	1	6%	20%
6	2D20	Approval/control of AFM/AFMS	1	6%	17%
7	4D2	Major/minor determination	1	6%	14%
7	5D1	Approval of certification tests	1	6%	14%
7	6D2	Conformity inspections documented	1	6%	14%
8	9D12	Approval of service bulletins and maint. manuals	1	6%	17%
		TOTAL	**17**		

TABLE C- 15.— Isolated observations – DAS facilities

Rank	Criteria	Name	Number Of Isolated Observations	Percent Of All Isolated Observations for DAS facilities	Percent Of All DAS Facilities That Had Isolated Observations
1	2D21	TIR/STIR to document conformity, inspection, and tests	1	25%	14%
1	2D27	Documentation/approval of type design data	1	25%	14%
1	3D3	Classification of data being approved	1	25%	14%
2	3D2	Use of approved documents and forms	1	25%	13%
		TOTAL	**4**		

TABLE C- 16.—Systemic findings and observations – SFAR-36 facilities

Rank	Criteria	Name	Number Of Systemic Findings And Observations	Percent Of All Systemic Findings And Observations for SFAR-36 facilities	Percent Of All SFAR-36 Facilities That Had Systemic Findings And Observations
1	2D1	Certification basis established	1	100%	50%
		TOTAL	**1**		

TABLE C- 17.— Isolated observations – SFAR-36 facilities

Rank	Criteria	Name	Number Of Isolated Observations	Percent Of All Isolated Observations for SFAR-36 facilities	Percent Of All SFAR-36 Facilities That Had Isolated Observations
		TOTAL	**0**		

No isolated observations were reported for SFAR-36 delegations in FY 1999.

TABLE C- 18.—Systemic findings and observations – DOA facilities

Rank	Criteria	Name	Number Of Systemic Findings And Observations	Percent Of All Systemic Findings And Observations for DOA facilities	Percent Of All DOA Facilities That Had Systemic Findings And Observations
1	1D16	Training of delegated facility staff	1	100%	100%
		TOTAL	**1**		

TABLE C- 19.— Isolated observations – DOA facilities

Rank	Criteria	Name	Number Of Isolated Observations	Percent Of All Isolated Observations for DOA facilities	Percent Of All DOA Facilities That Had Isolated Observations
		TOTAL	**0**		

No isolated observations were reported for DOA delegations in FY 1999.

APPENDIX D
THE RELATIONSHIP BETWEEN FACILITY COMPLEXITY AND THE PROBABILITY OF SYSTEMIC ISSUES

When a direct comparison among facilities types is made, PC holders appear to have a higher percentage of facilities in noncompliance than other facility types. They also have more findings and observations. However, we believe that this direct comparison among the facility types is biased. There is very strong evidence that regardless of facility type, larger facilities with complex systems have a greater chance of having findings and observations than small facilities with simple systems. For example, a 20,000-employee manufacturer of a complex assembly has a greater chance of having discrepancies than a four-employee manufacturer of a simple part– simply due to the differences in their sizes and nature of their systems. There are only a handful of PC holders with a small number of employees and operating under simplistic quality systems. However, numerous PMA holders and TSO authorizations are small and operate under simple systems. Therefore, comparing PC holders to PMA or TSO facilities without compensating for their varying size and complexity would be inappropriate. The obvious solution would be to compare facilities of similar size and complexity.

The number of evaluators, duration of the evaluations, total evaluator hours expended, and the size of the facilities were all explored as possible measures of facility complexity. In analyzing FY 1999 data, the duration of the evaluations, total evaluator hours, and the number of evaluators were all related to the probability of issues. However, only the number of evaluators was a consistently reliable parameter for all of the five years the trend analyses cover. Additionally, in those years where all three parameters were viable, the elimination of duration and total evaluator hours from the models did not substantially change the strength of the models. Using all three parameters would have unnecessarily complicated the model while adding almost no additional strength to the model. There was insufficient data to use facility size or other demographic information concerning the facilities to make these parameters viable.

Therefore, the number of evaluators was chosen as the most reliable indicator of facility complexity. The number of evaluators selected to conduct an ACSEP evaluation is determined prior to the evaluation with careful consideration to: a facility's size, physical layout, number and types of certificates held, number of applicable system elements, product number and complexity, number of employees associated with these products, the number of procedures controlling these products, and any unique or special circumstances. Consequently, the number of evaluators would be a very comprehensive indicator of facility complexity.

It should be noted that the number of evaluators is neither a guarantee of findings nor is it in itself the determinant of the probability of a facility having findings recorded. There were several occurrences of large evaluation teams not finding any systemic issues and

several occurrences of small evaluation teams finding several systemic issues. This would support the theorem that the number of evaluators is only an indicator of facility complexity. By possessing a greater number of procedures and policies, more complex systems would have a higher probability of being in noncompliance. The number of evaluators is a measure of facility complexity; complexity relates to the number of possibilities for noncompliance; the number of possibilities for noncompliance defines the probability for noncompliance; and the probability for noncompliance determines the number of findings.

APPENDIX E
ANALYSIS METHODS AND ASSUMPTIONS

E1. Sample/Inferential Error

One of the purposes of an ACSEP evaluation is to test a facility's compliance with the CFR and its own established policies and procedures. In a very small facility with very few procedures and low production, the test for compliance could be a 100 percent check of all available data. For all other facilities, however, a 100 percent check of all available data would be extremely time consuming, uneconomical, and disruptive to the facility's productivity. For all except the smallest of facilities, ACSEP uses the widely accepted practice of examining only a portion of the available documentation and extrapolating the results to conclusions about the balance of the documentation not reviewed. The examination of a small portion of the available documentation and drawing conclusions about the whole of a facility's documented system is defined as a sampling process.

Any inference to the population based upon this sample has the possibility of slight error. There is no guarantee that the sample of documentation selected during the evaluation will exactly reflect the condition of all of the available documentation; just as there is no guarantee that ten flips of a fair coin will always result in five heads and five tails.

The charts in this report reflect the exact results of the evaluations performed within the time period specified. Statements as to the compliance rate of those particular facilities evaluated can be made directly off the figures and tables. However, using the data from the evaluations analyzed in this report to predict industry trends, as opposed to simply reporting historical results, is subject to the statistical principle of sample error.

Using *figure 3-13* as an example, 22 percent of the production approval holders evaluated for FY 1999 had systemic manufacturing process issues. In addition, the data can be used to predict, within a 95 percent confidence level, that no less than 18 percent and no more than 26 percent (22 percent ± 4 percent) of *all* production approval holders have systemic compliance issues in manufacturing processes. Please note that the four percent error is only a measure of the reliability of predictions based on the data and is not a measure of the accuracy of the data itself.

E2. Sample/Inferential Error When Reporting the Number of Noncompliances

As stated earlier, time and resources limit the amount of documentation that can be evaluated at any one ACSEP evaluation. The ACSEP team uses judgment to select those documents to evaluate that best represent the total system being evaluated. The use of sampling, good evaluation judgment, and skilled evaluators will produce an evaluation report that statistically reflects compliance issues for a particular facility for a particular period of time. However, these limiting factors also limit the total number of potential

findings and observations reported. Given unlimited time and resources, there theoretically could be an indeterminate number of findings or observations. Lacking a finite number of possible findings or observations, the population size of possible findings or observations is, therefore, assumed to be large. Based on this assumption, the equation used to calculate the prediction error is:

$$PE_{\%} = \pm z\sqrt{\frac{p(1-p)}{n}} \qquad (1)$$

where $PE_{\%}$ = prediction error
z = confidence coefficient factor
p = percent of facilities with findings and/or observations
n = sample size (number of finding and/or observations)

Equation (1) proves adequate if the sample size is equal to or greater than 30. Should the sample size be less than 30, or p is either close to zero or one-hundred percent (if the product $pn < 5$ or the product $(1\text{-}p)n < 5$), equation (2) is more accurate in determining the limits of the analysis.

$$p_{\text{lim}} = \frac{p + \frac{z^2}{2n} \pm z\sqrt{\frac{p(1-p)}{n} + \frac{z^2}{4n^2}}}{1 + \frac{z^2}{n}} \qquad (2)$$

where p_{lim} = upper and lower confidence limit of the analysis
z = confidence coefficient factor
p = percent of facilities with findings and/or observations
n = sample size (number of finding and/or observations or the number of facilities considered satisfying the condition being tested)

E3. Sample Error When Reporting Facility Frequencies and Other Finite Populations

In those cases when the population is known and it is sampled without replacement, the above equations may overstate the inferential error. This is especially true when the sample size is greater than five percent of the population size. In order to not overstate the error for finite populations, Equation (1) is modified as follows:

$$SE_{\%} = \pm z\sqrt{\frac{p(1-p)}{n}}\sqrt{\frac{N-n}{N-1}} \qquad (3)$$

where $SE_{\%}$ = sample error
z = confidence coefficient factor
p = percent of facilities with findings and/or observations
n = sample size (number of finding and/or observations or the number of facilities considered satisfying the condition being tested)
N = population size

Equation (2) is modified as follows:

$$SE_{\%} = \left(\frac{p + \frac{z^2}{2n} \pm z\sqrt{\frac{p(1-p)}{n} + \frac{z^2}{4n^2}}}{1 + \frac{z^2}{n}} - p \right) \left(\sqrt{\frac{N-n}{N-1}} \right) \qquad (4)$$

where $SE_{\%}$ = sample error
z = confidence coefficient factor
p = percent of facilities with findings and/or observations
n = sample size (number of finding and/or observations or the number of facilities considered satisfying the condition being tested)
N = population size

The above formulas are used for the analyses reported in Sections 3.6 through 3.10. For the analyses reported in Section 3.5, the calculations for error are very complex and

performed automatically by the statistical software. Please refer to the SAS[11] user manual for additional information on how standard error is calculated.

E4. Pooling of Multi-year Data

The pooling of two fiscal years of data is considered a justifiable method of strengthening the reliability of the analyses since it does not introduce any additional variants into the analysis. Because the shortest time interval between an ACSEP evaluation being repeated at any one facility is two years, pooling of two years of data represents an analysis of only one evaluation from any one facility[12]. Therefore, data from two consecutive years are considered to be from the same total population and pooling the two sets of data in some of the analyses used in this report is considered justified.

In the case of PC holders, the pooling of two fiscal years of data is considered necessary to obtain a random sample of facilities for analysis. The compliance levels for PC holders appear to rise and fall in a two-year cycle. This is theorized to be caused by a facility selection bias initiated (see *Section 3.8.1*) in FY 1993 when ACSEP first transitioned from QASAR (see *Appendix A*). In order to counteract the affects of the biannual cycle, data from two consecutive years is used.

E5. Selection of the Confidence Interval

The conclusions reached in this report are based on analyses of a finite set of data (i.e., sample data). Statements made concerning probability distributions of the true population are based upon the results of this sample data and are thereby subject to statistical, or inferential, error. This inferential error is divided into two types: noting a significant difference in the samples when there is none — Type I error, and the failure to note a significant difference when a significant difference does exist — Type II error. Attempts to limit the probability of Type I error (denoted by α) generally increase the likelihood of Type II error (denoted by β). The only way to simultaneously eliminate both types of error is to increase the sample size. The confidence intervals selected for the individual analyses attempt to balance the possibility of these two types of error. In those analyses where one type of error may have more serious consequences than the other, a confidence level is selected to limit the more severe of the two error types.

Analysis performed on the data to determine the frequency distribution of the findings and observations divides the data into several discrete categories, i.e., 17 system elements. In addition, the sample sizes are relatively low; e.g., the sample size of domestic PC holders for FY 1999 is 25 facilities having a total of 81 systemic issues among them. This already small sample size is further divided into the occurrences

[11] SAS is a registered trademark of SAS Institute, Gary, NC 27513. Version 8 was used for the analyses of this report.

[12] In some isolated cases the frequency between evaluations is 16 months. Care is taken to avoid double accounting for these isolated occurrences.

within 17 system elements and 228 different criteria. A 95 percent confidence interval was used in order to highlight the differences among the various system elements while maintaining a reasonable limit of Type II errors.

Some of the analyses in this report test for significant differences among a few (typically four or less) proportions in an attempt to highlight potential variations in the samples. Because of the consequences associated with Type II errors in analyses of this type, i.e., not noting a trend and consequently not acting on that trend, an emphasis is placed on limiting Type II errors and less emphasis is placed on Type I errors. Decreasing β, however, correspondingly increases α— the probability of Type I errors. The level of significance is therefore increased to $\alpha = 0.10$ rather than using $\alpha = 0.05$ used for the analyses mentioned earlier. The confidence level is accordingly set at 90 percent — $100*(1-\alpha)$.

Increasing α simultaneously reduces β — the probability that a difference in the distributions or a trend will be erroneously missed. The probability of Type I and Type II errors (α and β) is simultaneously reduced through the pooling of two consecutive fiscal years of data and by eliminating known outside variants, e.g., facility complexity. Therefore, by applying a 90 percent confidence level on carefully selected and pooled data, trends can be spotted and acted upon as soon as possible while maintaining a reasonable limit on Type I errors. A confidence level of 90 percent is used in all comparisons of the approval types and trend analyses.

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